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No.

IN THE

Supreme Court Of The United States

OCTOBER TERM, 1988

9/1 KG CONTAINERS, MORE OR LESS,
OF AN ARTICLE OF DRUG FOR VETERINARY USE,
AND SCHUYLER LABORATORIES, INC.,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. Whether the Food and Drug Administration ("FDA") is empowered to control the manner in which veterinarians use medicines to treat their patients.

2. Whether bulk drug ingredients intended to be compounded by veterinarians solely in the course of their professional practices can be exempt from the statutory requirement to bear "adequate directions for use" under FDA's bulk drug regulation, 21 C.F.R. §201.122 (1988), or whether such drugs are unapproved "new animal drugs" and therefore may not be purchased by veterinarians until a new animal drug application has been approved by FDA for each use that the veterinarian will make of the drug.

LIST OF ALL PARTIES TO THE PROCEEDING

All parties in the proceeding appear in the caption of the case. Schuyler Laboratories, Inc., is an independent company and has no parent company, subsidiary or affiliate. In addition to the parties to the proceeding, the following were *amici curiae* in the Seventh Circuit: the American Feed Industry Association, a national trade association representing manufacturers and distributors of animal feeds and animal drugs; the American Food Animal Veterinary Medical Association, an association of food animal veterinarians; and the Animal Health Institute, a national trade association representing manufacturers and distributors of animal drugs.

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PETITION FOR WRIT OF CERTIORARI

Petitioners respectfully seek a writ of certiorari to review the opinion and order of the United States Court of Appeals for the Seventh Circuit ("Seventh Circuit").

OPINION BELOW

The opinion of the Seventh Circuit has not yet been reported; it is reproduced in the appendix ("App."). *United States v. 9/1 Kg Containers*, No. 88-1233 (7th Cir. July 27, 1988). App. 1a. The district court's decision is reported at 674 F. Supp. 1344 (C.D. Ill. 1987). App. 11a.

JURISDICTION

The judgment of the Seventh Circuit was entered on July 27, 1988. App. 25a. A petition for rehearing was denied on September 6, 1988. App. 26a. On September 30, 1988, the Seventh Circuit stayed the issuance of its mandate until October 12, 1988. App. 32a. The Seventh Circuit's order provides that its Stay will continue until final disposition of the petition if by October 12,

1988, a petition for a writ of certiorari is filed. *Id.* Jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

STATUTES AND REGULATIONS INVOLVED

This case chiefly involves the Federal Food, Drug, and Cosmetic Act ("FDC Act") §§201(w), 502(f) and 512(a)-(b), 21 U.S.C. §§321(w), 352(f), and 360b(a)-(b), and Title 21 of the Code of Federal Regulations, especially 21 C.F.R. §201.122. These are reproduced in the appendix. App. 27a.

STATEMENT OF THE CASE

The government seeks condemnation of bulk drugs that are intended solely for use by veterinarians to treat animals in the course of their licensed practices. The drugs, owned by petitioner Schuyler Laboratories, Inc. ("Schuyler"), were seized and remain in custody.

The purity, identity and proper strength of the drugs are not challenged and most are common, well-known products that have been used for years. Their value exceeds $200,000.00.

1. Statutory And Regulatory Framework

The FDC Act and two other statutes dealing specifically with biologic drugs[1] establish a comprehensive system for regulating drugs intended for both animal and human use, and those who manufacture such drugs for commercial purposes. Drugs that are adulterated or misbranded are subject to seizure, 21 U.S.C. §334 (1982), and persons who violate the law may be enjoined, 21 U.S.C. §332 (1982), or criminally prosecuted, 21 U.S.C. §§331, 333 (1982). Drug manufacturers are required to register annually with the FDA, 21 U.S.C. §§360(b) and (c) (1982), and must also list with FDA on a semi-annual basis all drugs they have distributed commercially, 21 U.S.C. §360(j) (1982). Drug manufacturers are also subject to extensive recordkeeping requirements, 21 U.S.C.

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[1] A biologic animal drug is a serum, vaccine, toxin or antitoxin that is intended for use in the treatment of domestic animals. 21 U.S.C. §151 (1982 & Supp. IV 1987). Animal biologics are approved by the United States Department of Agriculture under the Virus-Serum-Toxin Act, 21 U.S.C. §§151-159 (1982 & Supp. IV 1987), and human biologics are approved by FDA under the Public Health Service Act, 42 U.S.C. §262 (1982). As their name suggests, biologic drugs are products of biologic origin as opposed to drugs that are chemicals.

§351(a)(2)(B) (1982) and 21 C.F.R. Part 211 (1988), and FDA may inspect facilities in which drugs are manufactured or held, 21 U.S.C. §374 (1982).

The FDC Act has from the beginning treated commercial drug producers and practitioners differently. Congress has broadly excluded veterinarians and other practitioners from the requirements it has imposed on drug manufacturers. Practitioners are exempt from the registration requirement of the FDC Act when they "manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice." 21 U.S.C. §360(g)(2) (1982). Similarly, FDA has no authority to inspect the "records, files, papers, processes, and controls" of veterinarians and other practitioners who compound drugs for use in their practices. 21 U.S.C. §374(a)(1) and (a)(2)(B) (1982).

Certain drugs, known as "new drugs" or "new animal drugs," are subject to prior approval by FDA before they may be marketed. Drugs that are not "new" *are* nevertheless subject to all the other controls provided for in the statute. The FDC Act defines a "new animal drug" in part as one which is intended for use in animals other than man

> (1)the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience ... as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof ... or ...
>
> (3)which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof ....

21 U.S.C. §321(w) (1982).

> A "new animal drug" shall be deemed to be unsafe unless:
>
> (A)there is in effect an approval of an application filed pursuant to subsection (b) of this section [a new animal drug application or "NADA"] with respect to such use or intended use of such drug [and]
>
> (B)such drug, its labeling, and such use conform to such approved application ....

21 U.S.C. §360b(a)(1) (1982). An unapproved new animal drug is deemed "adulterated" and therefore subject to seizure. 21 U.S.C. §§351(a)(5) and 334 (1982).

The FDC Act requires that drugs, including biologic drugs, bear "adequate directions for use" unless they are exempted. 21 U.S.C. §352(f)(1) (1982). A proviso to section 352(f) states that where adequate directions for use are "not necessary for the protection of the public health, the Secretary [by delegation, FDA] shall promulgate regulations exempting such drug ... from such requirement." FDA has published a series of exempting regulations. 21 C.F.R. §§201.100-201.129 (1988).

The exemption at issue in this case is 21 C.F.R. §201.122 which provides:

> A drug in a bulk package, except tablets, capsules, or other dosage unit forms, intended for processing, repacking, or use in the manufacture of another drug shall be exempt from section 502(f)(1) of the Act if its label bears the statement "Caution: For manufacturing, processing, or repacking" .... But the exemption shall not apply to a substance intended for use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:
>
> (a)an approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder by persons named in the application ....

FDA regulates commercial drug manufacturers closely. In this case, the issue is whether medicines prepared and used by practitioners, who have stood outside the commercial drug approval system, may now be regulated in the same manner as those produced by commercial drug manufacturers.

2. Proceedings Below

The complaint[2] alleged that the seized goods were misbranded under 21 U.S.C. §352(f)(1) because they failed to bear "adequate directions for use." FDA asserted that the seized

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[2] Jurisdiction in the district court was invoked under 28 U.S.C. §1345 and 21 U.S.C. §334.

materials became unapproved "new animal drugs" when they were compounded into medicines by veterinarians and that therefore they cannot be exempt from the labeling requirement when shipped in bulk to veterinarians. The district court agreed with Schuyler that the bulk materials were not misbranded when sold to veterinarians and labeled "for manufacturing, processing, or repacking" in accordance with the FDA regulation exempting bulk products from the adequate directions for use requirement, 21 C.F.R. §201.122.[3] App. 23a.

The district court's opinion proceeded from a finding that the Congress had not intended that FDA should exercise authority over veterinarians in their medical decisions concerning drug therapy.[4] App. 19a. The professional use of veterinary medicines is not lawfully regulated under the "new drug" provisions, which would require prior approval for each and every patient treatment. App. 21a. The district court noted that the interpretation of the statute urged by FDA would "establish for the first time that it [FDA] is empowered to control an integral part of veterinary practice [*i.e.*, the prescribing and compounding of veterinary drugs]." App. 22a. The district court held that "Congress has *never* attempted to handcuff veterinarians in such a way and neither will this Court." App. 23a.

The reversal by the Seventh Circuit was based upon an entirely different reading of the legislative history of the FDC Act. App. 5a. The Seventh Circuit read the FDC Act to leave only matters of medical licensure and discipline to the states, and to give FDA control of the drug treatment choices and therapies of all medical practitioners. *Id.* In *dictum* the Seventh Circuit stated its view that practitioners were not sufficiently knowledgeable to use

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[3] FDA also contended that five lots of bulk antibiotics were adulterated because, as a matter of law, they were specifically named in the FDC Act as "new animal drugs," which required but did not have FDA approval. 21 U.S.C. §321(w)(3) (1982). The district court ruled they are not unapproved new drugs, App. 24a, and the Seventh Circuit did not reach this issue, App. 2a.

[4] In an injunction action based on the same legal issue in the District of New Jersey, the district court reached the same conclusion. *United States v. Algon Chemical, Inc.*, No. 87-1820 (D. N.J. April 12, 1988), *appeal docketed*, No. 88-5478 (3d Cir. June 17, 1988). App. 34a.

drugs safely without FDA supervision, and that tort relief against those practitioners who made mistakes would be insufficient to pay for injuries that might result (and inferentially that commercial houses would be able to pay or would be more responsible). App. 6a.

3. The Deleterious Effects of FDA's Proposed Interpretation Are Uncontested

The Seventh Circuit took it "as given that for significant diseases there are no effective FDA-approved drugs." App. 1a. This language and the examples cited by the court do not adequately describe the undisputed and unmitigated disaster that would occur if the Seventh Circuit opinion is the law; plainly more is involved than that "[m]any veterinarians find this state of affairs deplorable." App. 2a.

The record documents fully the practical consequences of permitting the control FDA contemplates. FDA did not attempt to controvert the following facts.

Like all practitioners of the healing arts, veterinarians must be able to prescribe and compound drugs for their patients.[5] Each of the healing professions, veterinary medicine included, is an art. Diseases and animals do not react to medicines with mechanical precision.[6] The efficacy of medicines will vary widely with individual animals and with diseases; a drug that is effective in one geographic area might simply not be as effective elsewhere for the same disease.[7]

The Seventh Circuit decision may have devastating consequences for the animals that provide the basics of the American food supply.[8] Acute mastitis, a disease that can destroy dairy *herds* within hours, cannot be treated effectively with FDA-approved

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[5] *See, e.g.*, Clack Statement at ¶¶3, 4, and 7, Supplemental Appendix of Appellees filed in the Seventh Circuit ("Appellees' S.A.") at 22-24.

[6] Clack Statement at ¶7, Appellees' S.A. at 23-24; Crouch Statement at ¶6, Appellees' S.A. at 28-29.

[7] *Id.*

[8] Clack Statement at ¶8 and attachment, Appellees' S.A. at 24, 26; VanDamme Statement at ¶¶5-7, Appellees' S.A. at 37-38.

remedies.[9] Nor can veterinarians treat the highly contagious respiratory infections that will kill an estimated 75% to 80% of affected calves unless they can compound effective medications.[10] Shipping fever and salmonella infections in feedlot cattle cannot be treated effectively with FDA-approved drugs.[11] There is no FDA-approved anesthetic that can be used in the field to do general surgery on food animals.[12] (Can FDA *really* intend that veterinarians engage in such an inhumane practice as performing surgery without an anesthetic?) There are no FDA-approved medicines for most of the diseases that afflict economically important nonfood species such as mink and fox.[13]

ARGUMENT

I. THE SEVENTH CIRCUIT'S INTERPRETATION OF THE FDC ACT RAISES IMPORTANT QUESTIONS REGARDING THE ADMINISTRATION OF THAT LAW

This case merits Supreme Court review. For the first time since the enactment of the basic Act fifty years ago, a court has ruled that a vital aspect of the practice of the healing arts, patient drug therapy, is directly within the authority of the Food and Drug Administration. Specifically, the Seventh Circuit has ruled that the agency may exert prior approval authority over each and every medicine used on patients by a veterinarian in his practice. The sweep of the opinion is such that it covers any medical practitioner, including physicians, who use drug therapy.

The effect of the ruling is to make it unlawful for veterinarians to use medicines in their practices until and unless a

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[9] VanDamme Statement at ¶7, Appellees' S.A. at 37-38; *9/1 Kg Containers*, App. 2a.

[10] VanDamme Statement at ¶6, Appellees' S.A. at 37. A major reason for the ineffectiveness of approved drugs where they exist is that the FDA-approved use of these drugs by laymen has led to resistance. Clack Statement at ¶6, Appellees' S.A. at 23.

[11] Skiles Statement at ¶¶4-5, Appellees' S.A. at 31-32; *9/1 Kg Containers*, App. 2a.

[12] Clack Statement at ¶8, Appellees' S.A. at 24; *9/1 Kg Containers*, App. 2a.

[13] Westlake Statement at ¶7, Appellees' S.A. at 41-42; *9/1 Kg Containers*, App. 2a.

commercial interest has seen fit to secure approval of a drug for the specific disease and the species that is affected by the disease. Even the use of an approved drug for an unapproved purpose is unlawful under the Seventh Circuit's decision. But veterinarians and other health care professionals cannot use the new drug approval system at the agency; it is geared to commercial enterprises. App. 8a.

The decision thus gives effect to a regulatory scheme that the director of FDA's Center for Veterinary Medicine acknowledges is inconsistent with the ethical practice of veterinary medicine. Appellees' S.A. at 69-71. The undisputed record thus establishes that veterinarians must disobey the law to prevent a health catastrophe.

This is clearly an instance when a "federal court of appeals has decided an important question of federal law which has not been, but should be, settled by this Court." Sup. Ct. R. 17.1(c). No court decision has ever before interpreted the FDC Act to permit the government to exert such complete control over the way practitioners treat their patients. The Seventh Circuit's ruling would create considerable change in the way FDA regulates under the FDC Act (the Seventh Circuit's opinion noted the vulnerability of "thousands of individual veterinarians" to prosecution, App. 2a), and would increase exposure to civil liability for those practitioners who exercised proper medical judgment to prescribe beyond FDA-approved labeling. The ruling affects health care for human beings and animals, and also the nation's food supply. The need for this Court to settle the matter is apparent.

II. THE SEVENTH CIRCUIT'S DECISION RESTS ON A NOVEL AND INCORRECT INTERPRETATION OF THE FDC ACT

A. The FDC Act Was Not Intended To Regulate The Practice of Medicine

Neither the language nor the legislative history of the FDC Act supports a finding that FDA must give prior approval to medicines compounded by veterinarians. The legislative history

establishes beyond any possible doubt that the FDC Act was *not* intended to regulate the practice of any of the healing arts.

The Seventh Circuit held that the district court erred in its conclusion that "it was not the purpose of the Act to involve the agency in the practice of the healing arts," and held that the Act allows FDA to make the ultimate determination for any drug, even drugs used by licensed practitioners to treat individual patients, as to whether such drug is "ineffective or dangerous." App. 5a. The Seventh Circuit reached its conclusion based on its finding that the FDC Act was intended "to regulate drugs," this Court's ruling in *United States v. Rutherford*, 442 U.S. 544 (1979), and on one phrase in the legislative history of the basic 1938 Act. The phrase appeared in a 1935 Senate Report and stated that the Act was "not intended as a medical practices act and [would] not interfere with the practice of the healing art *by chiropractors and others*." *Id.*[14] According to the Seventh Circuit, this passage "makes the point" that Congress intended only to avoid interference with practitioners who do not use drugs in their practices. *Id.*

In the fifty years since the FDC Act became law, courts, FDA, and legal experts have on other occasions reviewed the legislative history of the Act, and all of them have reached a different conclusion than that reached by the Seventh Circuit. An analysis of the legislative history of the 1938 FDC Act shows that the Seventh Circuit's opinion has overlooked portions of that history that render its analysis incorrect.[15]

The proposed legislation which ultimately became the 1938 FDC Act was first introduced in 1933, "and was immediately ques-

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[14] Quoting S. Rep. No. 361, 74th Cong., 1st Sess. 3 (1935), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. III at 660 (emphasis added by the Seventh Circuit).

[15] It is curious that the Seventh Circuit, after saying that it was required to defer to an agency's interpretation of its governing statutes, App. 5a, used this language from the legislative history to support a statutory interpretation that FDA never made. In the court below FDA had contended that the 1968 Animal Drug Amendments, not the 1938 FDC Act, gave it the authority to require approval of compounding by veterinarians. *See* discussion of the 1968 Animal Drug Amendments, *infra* at 15.

tioned by parts of the medical profession as an attack upon the prerogatives of the physician." Hutt, *Regulation of the Practice of Medicine Under the Pure Food and Drug Laws*, 33 Assoc. of Food and Drug Officials Q. Bull. 8 (1969). As a result of this concern, the definition of the term "drug" was amended to add the words, "and not to regulate the legalized practice of the healing art." S. 2800, 73rd Cong., 2d Sess. 2 (1934), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. II at 671.

As Senator Copeland, the bill's sponsor, explained:

> There was a feeling on the part of certain divisions of the medical profession that there was an attack upon the prerogatives of the doctor, particularly of the chiropractors .... [T]his bill makes certain that the medical practitioner shall not be interfered with in his practice.

78 Cong. Rec. S2728-29 (daily ed. February 19, 1934), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. I at 800.

Senator Copeland's statement, combined with the amended language of the Act to which he referred, demonstrates that when Congress precluded regulation of the practice of medicine it did not mean merely those practices that did not entail the use of drugs. Had Congress intended to avoid only the regulation of chiropractors, the amended language would have reflected this intent. The broad language used by Congress, and Senator Copeland's concluding statement that "this bill makes certain that the medical practitioner shall not be interfered with in his practice," demonstrate the *certain* intent of Congress to avoid regulating the treatment decisions of all practitioners of the healing arts, including those who use drugs.[16]

Any doubt as to Congress' intent to avoid regulation of the prescriptions of licensed practitioners was removed in subsequent

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[16] The term "medical profession" was defined in the 1934 version of the Act to mean "the professions of medicine, pharmacology, dentistry [and] veterinary medicine." S. 2800, 73rd Cong., 2d Sess. 2 (193-), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. II at 671.

debate of the Act. In 1935 Senator Lewis, showing his desire to avoid regulating the medicines used by licensed practitioners, attempted to exclude from the term "drug" any "medicine *prepared* and dispensed by a physician in the course of his professional practice." 79 Cong. Rec. S5019 (daily ed. April 5, 1935), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. IV at 57 (emphasis added). However, Senator Copeland assured Senator Lewis that the word "drug" was not intended to apply to the preparations of a physician dispensed in the course of his practice:

> *Mr. Copeland.* The matter the Senator from Illinois has in mind is whether or not this measure interferes at all with a written prescription of a doctor.
>
> *Mr. Lewis.* The word "drug" is not intended to apply to preparations dispensed by a doctor himself in the course of his professional practice.
>
> *Mr. Copeland.* There is nothing in the bill which would interfere at all with the ordinary legal practice of the profession.

Id.

This debate, which has none of the qualifications that the Seventh Circuit read into the phrase it relied upon, shows conclusively that Congress intended to refrain from any regulation that would impinge on the treatment decisions of licensed practitioners, decisions that Congress recognized are tailored to the patients' needs, *including* what medications work best for that individual. The Seventh Circuit overlooked this vital commentary.

A former chief counsel of FDA concluded in his analysis of the legislative history of the 1938 Act:

> Through the six years of legislative history the proposed legislation contained the affirmative requirement that every drug must bear adequate directions for use. Not only does the legislative history fail to show a Congressional intent that this be used to restrict the conditions for which physicians might prescribe drugs, but it flatly contradicts any such interpretation.

Hutt at 9.[17] As recently as a few years ago, FDA was arguing that the intent of Congress was not "to limit a physician's ability to treat his patients." *Chaney v. Heckler*, 718 F.2d. 1174, 1179 n.13 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985). The Seventh Circuit ruling contradicts this.

B. The Drug Amendments Act Of 1962 Specifically Exempted Practitioners From New Requirements Imposed On Commercial Enterprises

Actions of Congress subsequent to the passage of the basic FDC Act have been entirely consistent with what FDA in 1983 called the "commonly recognized exemption to the Act's broad and protective coverage: the 'practice-of-medicine' exemption." *Chaney*, 718 F.2d at 1179. The Drug Amendments Act of 1962 made comprehensive changes in the FDC Act and greatly increased FDA's ability to regulate commerce in pharmaceuticals intended for both human and veterinary use. Pub. L. No. 87-781, 76 Stat. 780 (1962), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIII at 228. Prior to 1962, "new drugs" had to be approved on the basis of safety alone. The 1962 Amendments added the requirement that a manufacturer demonstrate effectiveness as well as safety before FDA would approve a "new drug" for marketing. *Id.*; 21 U.S.C. §355 (Supp. III 1985). Congress also significantly expanded FDA's inspection authority, 21 U.S.C. §374, and required that manufacturers of pharmaceuticals register with FDA, 21 U.S.C. §360.

While expanding FDA's power over commercial drug production in 1962, the Congress at the same time carved out exclusions from FDA's authority for the express purpose of keeping the regulator out of the practice of the healing arts. Nowhere in the 1962 Amendments or in their legislative history did Congress indicate that FDA could regulate the prescribing and compounding practices of physicians and other practitioners. There is not one whit of evidence to support FDA's argument that the com-

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[17] Mr. Hutt is the co-author of a casebook on food and drug law, *Food and Drug Law -- Cases and Materials* (1979).

pounding or use of medicines in professional practices created a "new drug," nor is there any evidence that Congress intended in any way to backtrack from the protections it accorded to practitioners under the 1938 Act.

In 1962, Congress increased FDA's authority to allow it to inspect extensively "any factory, warehouse, [or] establishment" in which *prescription* drugs are made. 21 U.S.C. §374(a)(1)(B). At the same time, Congress specifically exempted from this increased inspection authority "practitioners licensed by law to prescribe or administer drugs ... who manufacture, prepare, propagate, compound, or process drugs ... solely for use in the course of their professional practice." 21 U.S.C. §374(a)(2)(B).

The 1962 Amendments also defined for the first time the terms "manufacture, preparation, propagation, compounding, or processing" and required persons who engaged in those activities to register annually. 21 U.S.C. §360(a) and (b).

> The purpose of this provision is to assist the Food and Drug Administration to identify and inspect all places where drugs are being made, and to take appropriate action (by criminal proceedings, injunction, or seizure) against those who fail to register. *It would not apply to pharmacies, or to licensed practitioners preparing drugs in the course of their professional practice*, or to persons who prepare drugs solely for use in research, teaching, or chemical analysis, and not for sale.

S. Rep. No. 1744, 87th Cong., 2d Sess. 12 (1962), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXII at 105 (emphasis added). The FDC Act accordingly separates the practitioners from commercial manufacturers, and exempts from the registration requirement licensed practitioners who "prescribe or administer drugs ... and who manufacture, prepare, propagate, compound, or process drugs ... solely for use in the course of their professional practice." 21 U.S.C. §360(g)(2).

Congress thus explicitly recognized that compounding of medicines is not to be treated like commercial manufacturing operations and that the physician or veterinarian must be free to

use drugs in a manner consistent with the needs of patients. Because of this, the district court in this case found that to require veterinarians to apply for new drug approvals is simply unrealistic and inconsistent with Congress' intent to stay out of the regulation of veterinary medicine.

There is little said in the legislative history of the 1962 Amendments about the intent of Congress not to interfere in the practice of the healing arts. Because the registration and inspection exemptions merely gave effect to the basic Act's intent, not much discussion was necessary. The 1962 Amendments, rather than subjecting practitioners to the "new drug" approval scheme, emphasized and reinforced their exclusion from it.

The Seventh Circuit, however, concluded that these exemptions would not apply to "new drugs" just as they would not apply to stolen drugs, because the court reasoned that Congress' failure to specifically mention "new drugs" in the exemptions had no more significance than its failure to mention that stolen drugs were not exempt. App. 7a. This reasoning lifts the congressional action out of its context. Congress passed the 1962 amendments for the purpose of strengthening the new drug provisions; that was the focus of the legislation. If Congress had intended to limit the applicability of §360(g)(2) and §374(a)(2)(B) to "not new" and "grandfathered" drugs,[18] it could have done so easily.[19] Congress could have stated explicitly that the exemptions in §§360(g)(2) and

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[18] "Not new" or "old" drugs are those that are "generally recognized as safe and effective" for their intended uses. 21 U.S.C. §321(w)(1). The 1938 grandfather clause exempts from the new drug definition drugs that were on the market prior to 1938 and which contain "the same representations concerning the conditions of its use" that existed in 1938. *Id.* The 1962 grandfather clause exempts from the new drug definition drugs that were on the market in 1962, were generally recognized as safe at that time, and are offered for the same uses as in 1962. 21 U.S.C.A. §360b, Historical Note (1972).

[19] The Seventh Circuit did not mention the exemption in §374(a)(2)(B). However, the court's interpretation of the Act leads to the conclusion that Congress meant to require veterinarians to obtain new drug approvals for their compounded medications but that, through the exemption provided in §374(a)(2)(B), FDA could not inspect the process by which these "new drugs" were made, or alternatively, that the exemption applies only to "not new" and "grandfathered" drugs.

374(a)(2)(B) applied only to those situations in which there were drugs that were not "new drugs." Indeed, if veterinarians were to be registered and inspected while compounding one class of drugs and not another, the need to say so would have seemed undeniable.

Alternatively, Congress could have listed specific drugs that could be compounded by veterinarians, as it listed specific antibiotic drugs in 21 U.S.C. §321(w)(3). Congress did neither and there is nothing in the Act or the legislative history to indicate that Congress meant to limit the compounding exemptions to such a small and medically insignificant class of drugs.[20] Indeed, if the Seventh Circuit and FDA are correct that the compounding exemptions were intended to be so limited, there would have been no reason for Congress to have crafted such exemptions. The exemptions, read correctly, reaffirm Congress' intent to avoid interference with the treatment decisions of licensed practitioners.

The limited view the Seventh Circuit takes of the 1962 exemptions denies them the significance they warrant, both from their plain reading and from consideration of the circumstances in which they were put into the law.

C. The Animal Drug Amendments Of 1968 Did Not Confer On FDA The Power To Control Veterinary Medicine

The Seventh Circuit did not rely upon the legislative history of the Animal Drug Amendments of 1968, and rightly so. These amendments were enacted only to incorporate in one place the various statutory provisions that affected animal drugs.[21]

At the district court level, FDA, the expert agency to which the Seventh Circuit gave deference, did not argue that the 1938 Act expressed the intent that FDA could control the practice of veterinary medicine. Rather, FDA argued that the Animal Drug

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[20] FDA's own Director of the Center for Veterinary Medicine admits that there are no finished dosage form drugs useful to the practice of veterinary medicine that are "not new" or "grandfathered" drugs. Appellees' S.A. at 45-46.

[21] Pub. L. No. 90-399, §101(b), 82 Stat. 342, 343 (1968), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIV at 683.

Amendments, by adding 21 U.S.C. §360b, changed the congressional intent and authorized FDA to exercise prior approval authority over all compounding and prescribing by veterinarians. *See* FDA Brief in Opposition to Plaintiff's Memorandum in Opposition to Claimant's Motion for Summary Judgment at 13-15. FDA argued that this control existed for veterinarians only and not for the other healing professions, such as physicians, dentists, chiropractors, chiropodists, and pharmacists. *Id.* FDA contended that this provision, which states that the "use" of a new animal drug must "conform" to the use approved in a new animal drug application, 21 U.S.C. §360b(a)(1)(B), conferred the power to require approval of each and every use of a drug by a veterinarian. FDA Brief in Opposition at 13-15.

The Seventh Circuit implicitly recognized the invalidity of FDA's contention by ignoring it. Indeed, while the Animal Drug Amendments were being considered by Congress, FDA stated on several occasions that the amendments were simply a consolidation of existing law and did not provide any new regulatory authority. For example, according to the commissioner of FDA at the time, the legislation "doesn't provide any new authority ... but simply brings it together, gives visibility to the handling of animal drugs, animal feeds."[22]

D. Congress Has In Other Acts Reaffirmed Its Intent Not To Regulate The Way Veterinarians Make And Use Medicines

Congress' intent to distinguish between commercial manufacturers and practitioners, and to refrain from the regulation of medications used by veterinarians in their licensed prac-

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[22] *Animal Drug Amendments of 1967: Hearings on H.R. 3639 Before the Subcomm. on Public Health and Welfare of the House Comm. on Interstate and Foreign Commerce*, 90th Cong., 1st Sess. 26 (1967), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIV at 351. Furthermore, Congressman Jarman, chairman of the subcommittee that conducted the hearings on the animal health industry, emphasized that the bill would not "usurp any State authority." 113 Cong. Rec. H31,293 (daily ed. Nov. 6, 1967) (statement of Rep. Jarman), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIV at 477.

tices, has continued to be reaffirmed by actions taken *after* 1968. The Drug Listing Act of 1972, Pub. L. No. 92-387, 86 Stat. 559, *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIV at 930, required those who register with FDA as drug manufacturers to submit, semi-annually, a list of all drugs manufactured by them. The purpose of the bill was to allow FDA to compile "a comprehensive inventory of drugs so that FDA can better fulfill its role of assuring that [the drugs it regulates] are pure, safe, effective, and properly labeled."[23] The final bill extensively amended 21 U.S.C. §360, *but left intact* the exemptions pertaining to licensed practitioners. The drug listing requirement applies only to manufacturers that are required to register with FDA, and therefore veterinarians are exempt from the drug listing requirement. 21 U.S.C. §360(j).

The Seventh Circuit's opinion completely ignored the implications of Congress' 1985 amendments to the Virus-Serum-Toxin Act of 1913 ("V-S-T Act"). Congress' intent to avoid regulation of the medications used in the licensed practice of veterinary medicine is emphatically confirmed by the Food Security Act of 1985, which amended the V-S-T Act. Pub. L. No. 99-198, §1768, *reprinted in* 1985 U.S. Code Cong. & Admin. News (99 Stat.) 1354, 1654-56.

While the amending act gave the Secretary of Agriculture jurisdiction over all intrastate as well as interstate shipments of animal biologics,[24] Congress expressly directed that the Secretary exempt from the licensing requirements of the V-S-T Act those who prepare such biologics "solely for administration to animals under a veterinarian-client-patient relationship in the course of the State licensed professional practice of veterinary medicine ...." 21 U.S.C. §154a(2) (Supp. IV 1987). Congress' amendment to the V-S-T Act expressly allows veterinarians to prepare biologic drugs for treatment of their animal patients *without* prior approval of the federal government.

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[23] *Drug Listing Act, 1971: Hearings on S.2167 Before the Senate Comm. on Labor and Public Welfare*, 92nd Cong., 1st Sess. 14 (1971), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIV at 825.

[24] *See* 21 U.S.C. §§151, 154, 154a (1982 and Supp. IV 1987).

The inconsistency of this action with the finding of the Seventh Circuit is vivid. Congress has deemed it within veterinarians' professional abilities to prepare their own vaccines, a type of biologic drug, and to inject those vaccines into animals, including food-producing animals such as cattle and poultry. Yet, in stark contrast, the Seventh Circuit's holding makes it illegal for a veterinarian to compound even with aspirin and water. Could the Congress have ever intended to create such an inharmonious regulatory system?

There is no way that FDA can explain why Congress would intend that veterinarians can lawfully compound biologic drugs but not other drugs. Certainly, FDA cannot contend that biologics are inherently safer than drugs that are chemicals. One appellate court has specifically pointed out that control over biologic drugs such as vaccines is even more important than control over non-biologic drugs: "The purity of these substances [biologic drugs] is of far more importance than is the purity of ordinary drugs, because the former are ordinarily introduced into the circulation directly while the latter are introduced through the digestive tract." *Blank v. United States*, 400 F.2d 302, 303 (5th Cir. 1968) (quoting S. Rep. No. 1980, 57th Cong., 1st Sess. 2 (1902); H.R. Rep. No. 2713, 57th Cong., 1st Sess. 2 (1902)).

In the proceedings below, FDA elected not to attempt to explain why Congress would, on the one hand, allow veterinarians such latitude to practice and, on the other hand, would require that FDA approve of how veterinarians will use medicines. FDA's silence is an eloquent expression of its inability to reconcile these two enactments.

III. THE SEVENTH CIRCUIT'S INTERPRETATION OF THE ACT IS IN CONFLICT WITH OTHER JUDICIAL PRECEDENT

No other court has reached the conclusion of the Seventh Circuit. Indeed, all the precedent that involves active consideration of the subject recognizes that Congress did not intend that FDA should have the authority the Seventh Circuit conferred to control the practice of the healing arts.

In *Chaney v. Heckler*, 718 F.2d 1174 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985), the court considered whether FDA was required to approve drugs used in capital punishment. It is worth repeating that *FDA* argued in *Chaney* that the state-sanctioned use of lethal injections came within a "commonly recognized exception to the Act's broad and protective coverage: the 'practice-of-medicine' exemption." 718 F.2d at 1179. FDA maintained that the regulation of licensed practitioners by the states precluded FDA's regulation of the medications used in the context of licensed practices. *Id.* (FDA's position in 1988 is exactly the opposite, but the FDC Act has not changed, and certainly the history of the FDC Act has not changed.)

The District of Columbia Circuit, in an analysis that runs to a conclusion directly counter to the Seventh Circuit's, determined that the practice of medicine exemption stemmed from Congress' express intent to avoid regulation of licensed practitioners rather than from the States' licensing authority. The court stated that "the legislative history makes clear that Congress did not want to limit a physician's ability to treat his patients." *Id.* at 1179 n.13. The court stated further that "[t]he case law under this and related statutes is consistent with our reading of the legislative history." *Id.* at 1180 n.16 (citing *United States v. Evers*, 643 F.2d 1043, 1044 (5th Cir. 1981); *United States v. Moore*, 423 U.S. 122 (1975); *United States v. Collier*, 478 F.2d 268 (5th Cir. 1973)).

The court further explained the inapplicability of the drug approval process to the use of drugs by practitioners:

> The "new drug" provisions of [the Act] require the filing of a new drug application .... 21 U.S.C. §355(b). An applicant may have to wait up to six months for action and participate in hearings. *Id.* §355(c) & (c)(2). *Hence, these "new drug" provisions simply do not fit the reality of the clinical situation.*

Id. at 1180 n.15 (emphasis added).[25] In *Chaney*, the court, and apparently FDA, recognized that "Congress would have created

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[25] In his dissent in *Chaney*, then-Judge Scalia described as "extraordinary" the "notion that a person causes an article to be misbranded by simply using it for a purpose not stated on the label." *Id.* at 1199. This is exactly the effect of the

havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses." *Id.* at 1180.[26] The Seventh Circuit concluded that Congress intended veterinarians and other practitioners to be subject to the very new drug approval process that the *Chaney* court found would create that "havoc" in the licensed practices. App. 8a.

The Seventh Circuit decision is also in conflict with *United States v. Evers*, 643 F.2d 1043 (5th Cir. 1981). In that case, FDA charged that the defendant physician, Dr. Evers, misbranded a drug within the meaning of 21 U.S.C. §352(f)(1) when he advertised and dispensed it for use by his patients for purposes other than those approved by the FDA. The court recognized that "Dr. Evers' claims for his therapy are not generally accepted by the medical profession, and ... the FDA has not approved [the drug as used by Dr. Evers]." 643 F.2d at 1045. However, the court rejected FDA's contention that medications dispensed by physicians other than according to FDA-approved labeling were misbranded. *Id.* at 1053-1054. The Fifth Circuit recognized that FDA has no jurisdiction over the preparations of licensed practitioners, and that the determination of the safety and effectiveness of those preparations was not within FDA's authority.

The Seventh Circuit relied heavily upon *United States v. Rutherford*, 442 U.S. 544, 551-553 (1979), in which this Court held that the Act contained no exemption from the new drug approval process for drugs used to treat terminally ill cancer patients. The Court thus prohibited the interstate shipment of laetrile, a drug that FDA had determined, through an administrative hearing, was a "new drug." *Id.* The Seventh Circuit said the case stood for the proposition that physicians could not obtain laetrile for their use, and that the precedent controlled this case.

Seventh Circuit's decision: a veterinarian creates a misbranded new animal drug by the way in which he uses it to treat his patients.

[26] While *Chaney* involved the unapproved use of approved drugs, the discussion of whether the new drug provisions of the Act applied to the drugs used in medical practices to treat individual patients is equally applicable to the drugs in this case. The misbranding charge is based on the status of the *preparations* of veterinarians as "new drugs," not on the status of the seized products themselves.

The issues in *Rutherford* and in this case are not the same, because in that case there was no reason to consider the medical practice exemption. The Supreme Court in *Rutherford* did not consider whether the medications compounded by licensed practitioners for use in their practices are "new drugs." Indeed, the Supreme Court never considered *any* aspect of the practice of medicine in *Rutherford*.

In *Rutherford* this Court *did* say: "Exceptions to clearly delineated statutes will be implied only where essential to prevent 'absurd results' or consequences obviously at variance with the policy of the enactment as a whole." 442 U.S. at 552 (citations omitted). This Court then considered the legislative history and administrative interpretation of the FDC Act to find there was no exemption for the terminally ill. 442 U.S. at 552-59. Because it is so firmly developed in the legislative history and administrative interpretation of the FDC Act, the Seventh Circuit should have recognized the exemption for practitioners.

Pharmaceutical Manufacturers Association v. FDA, 484 F. Supp. 1179 (D. Del.), *aff'd*, 634 F.2d 106 (3d Cir. 1980), casts light on the proper bounds of FDA's authority. In *PMA*, the agency required the dispensing of information to patients about the drugs they were to take. *Id.* at 1181. The *PMA* court looked at the *quality* of the activity to conclude that the issue in the case was not about a "right to exercise judgment in prescribing treatment" but rather a "right to control patient access to information." *Id.* at 1188.

The quality of the activity that FDA would regulate in this case is something more than the withholding of information to which a patient is entitled. Indeed, the activity here is at the very core of the practice. So central is it that, if FDA gets the power it seeks, the ability to carry out that essential professional responsibility will be destroyed, and we all will suffer. No case can be found to support the proposition that it is within the power of FDA to control the practice of veterinary medicine from Washington.

Another court has looked at the issue tangentially in interpreting the Controlled Substances Act (CSA), 21 U.S.C. §§801-904. The First Circuit in *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987), recognized that Congress did not intend to control the

prescriptions of physicians through the CSA. That court considered whether a substance controlled by the Drug Enforcement Agency (DEA) could be deemed to have a "currently accepted medical use" if it had not been approved by FDA. The First Circuit rejected DEA's claim that "current medical use" meant FDA approval and stated that "it is plainly possible that a substance may fail to obtain ... approval even if it has an accepted medical use." *Id.* at 887. The First Circuit recognized that medical practice and research are not synonymous with FDA approval. *Id.*

IV. FDA'S INTERPRETATION OF THE ACT IS INCONSISTENT WITH PAST AND CURRENT POLICIES

The Seventh Circuit gave deference to the agency's *conclusion* that it should have authority over medicines compounded and used by veterinarians, finding the agency's authority in the history of the basic Act. In fact, the Seventh Circuit gave FDA authority that it did not argue that it should have (that is, over all practitioners who use drugs) and FDA did not argue that its authority came from the 1938 basic Act.

The agency to which the Seventh Circuit gave deference has accumulated a formidable record of inconsistency in dealing with the issue at hand. Past agency practice has actually tolerated compounding and in some cases expressly authorized it. The Seventh Circuit's decision also applies to human drug therapy and there it unequivocally contradicts FDA policy.

On October 10, 1944, FDA issued a regulation that exempted bulk drugs from the adequate directions for use requirement. 9 Fed. Reg. 12,255 (1944). That regulation authorized the shipment of bulk drugs to veterinarians and other practitioners and defined the term "manufacture" as excluding "the use of a drug as an ingredient in compounding any prescription issued by a physician, dentist or veterinarian in his professional practice." *See* 21 C.F.R. §2.106(k)(1), 9 Fed. Reg. at 12,256. Therefore, it is clear that FDA, although regulating bulk drugs, did not regulate the compounding of such drugs by practitioners.

More inconsistency is seen in FDA's compliance policy guides,[27] such as Compliance Policy Guide 7125.18, which is dated September 22, 1977, and is entitled "Human Drugs for Animal Use." Appellees' S.A. at 132. This guide was amended in 1980 and therefore was in effect until at least that time. (Petitioner does not know when or if this guide was revoked and FDA has not said.) The 1977 compliance policy guide stated that:

> [I]t is generally accepted that licensed veterinarians may compound their own prescriptions and may thus lawfully obtain prescription chemicals from pharmacy supply houses under local professional practice laws.

This policy attempted to balance the requirements of the FDC Act and "state laws and accepted practices governing the conduct of licensed practitioners." Appellees' S.A. at 133. In accordance with this policy FDA "has not in the past denied veterinarians the right to treat animals in accordance with the dictates of their conscience and within the bounds of accepted veterinary medical practice." *Id.* Although FDA did not *sanction* the use in a food-producing animal of a drug for which there is no specific FDA approval, FDA said that such use is the responsibility of the veterinarian. *Id.* FDA did *not* say that such use creates a new animal drug and is illegal. There is simply no way to square this compliance policy guide with FDA's current policy.[28]

In a 1976 FDA compliance policy guide, the agency stated that:

> [V]eterinarians may use in the compounding of prescriptions for their private practice whatever bulk drugs or other pharmaceuticals they may lawfully purchase. This falls under the general practice of veterinary medicine

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[27] FDA regularly issues documents that are known as compliance policy guides. Compliance policy guides state FDA's official opinions and are binding on FDA unless amended or revoked. 21 C.F.R. §10.85(e) (1988).

[28] FDA's most recent approach is stated succinctly in Compliance Policy Guide 7125.06, "Extra-Label Use of New Animal Drugs in Food-Producing Animals" (November 1, 1986): "The use or intended use of new animal drugs in treating food-producing animals in any manner other than in accord with the approved labeling causes the drugs to be adulterated ...." Appellees' S.A. at 119.

> which is amenable to local or State laws with which FDA has no desire to interfere.

FDA Compliance Policy Guide 7125.10, "Veterinarian Use of New Animal Drug Substances" (July 13, 1976), Supplemental Appendix for the Appellant in the Seventh Circuit at 30. FDA makes no mention, in this document, of any need for prior approval of the uses the veterinarian will make of these bulk materials, nor does FDA contend that a veterinarian's compounding would produce a violative, unapproved new animal drug.[29]

It is uncertain whether this compliance policy guide was intended to have any substantive meaning or whether its promulgation was simply a sham. The apparent general policy that a veterinarian can lawfully compound drugs is completely undercut if, as FDA seems to say, the veterinarian cannot legally receive the bulk drugs he needs to compound.[30]

The inconsistency of FDA's policy is demonstrated by the 1985 congressional testimony of a former director of FDA's Center for Veterinary Medicine:

> [P]rior to that time [1983 and 1984] the policy of the Food and Drug Administration for veterinarians was, and I quote:
>
> Veterinarians may use any drug they may legally obtain in their practices in accordance with their professional judgment and as long as they did not cause illegal residues.

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[29] This compliance policy guide says that it would not apply, however, to "bulk new drug or new animal drug substances." *Id.* The term "new animal drug substance" is an invention of the agency and cannot be found in the Act. FDA attempted, through this artifice, to regulate as "new drugs" those substances that would be used to produce new animal drugs.

[30] A third compliance policy guide adds to FDA's confusion. FDA states that: When a *bulk chemical* has a bonafide use in human or animal medicine not requiring approval, it may be shipped domestically or imported for that use provided it is not offered or intended for an unapproved use. Compliance Policy Guide 7125.20, "Availability of Bulk Chemicals for Animal Drug Use" (October 1, 1980), Appellees' S.A. at 137 (emphasis added). Because FDA does not approve bulk chemicals, the statement makes no sense.

> When we changed the policy, we tightened down on that considerably. We said no longer could veterinarians have the impunity to use any drug they could legally obtain.[31]

FDA's own statements, still "in effect," show why deference should not be given to an agency that plainly has no consistent policy. The Seventh Circuit's opinion makes clear that its rationale applies with equal force to *any* practitioner who uses drugs, including physicians; that is, the court says FDA has primary power over any drug therapy. App. 5a. But FDA, the expert agency, has, in language at dramatic variance to the Seventh Circuit decision, expressly rejected the notion that it has such authority. Speaking in the context of the unapproved use by physicians of marketed approved new drugs -- which could of course include compounding -- FDA says:

> Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.
>
> This interpretation of the Act is consistent with congressional intent as indicated in the legislative history of the 1938 Act and the drug amendments of 1962. Throughout the debate leading to enactment, there were repeated statements that Congress did not intend the [FDA] to interfere with medical practice and references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and patient.

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[31] *The Regulation of Animal Drugs by the Food and Drug Administration: Hearings Before the Subcomm. on Intergovernmental Relations and Human Resources of the House Comm. on Government Operations*, 99th Cong., 1st Sess. 263 (1985) (statement of Lester M. Crawford, Director, Center for Veterinary Medicine, Food and Drug Administration). This testimony proves the absurdity of FDA's claim that in 1962 Congress ratified FDA's present interpretation of 21 C.F.R. §201.122. Appellant's Brief in the Seventh Circuit at 30 n.35.

> Congress recognized a patient's right to seek civil damages ... if there should be ... malpractice, and declined to provide any legislative restrictions upon the medical profession.

37 Fed. Reg. 16,503 (1972). FDA repeated this interpretation of the FDC Act in 1987. 52 Fed.Reg. 8798, 8803 (1987). This FDA interpretation of the law and the legislative history of the basic Act and the 1962 amendments contradicts the Seventh Circuit, though the court considered that it was deferring to the agency's interpretation of the law.

It is clear that FDA has been anything but consistent.[32] Such inconsistency is not entitled to deference. *Adamo Wrecking Co. v. United States*, 434 U.S. 275, 287 n.5 (1978); *United Transportation Union v. Lewis*, 711 F.2d 233, 242 (D.C. Cir. 1983) ("[a] statutory construction to which an agency has not consistently adhered is owed no deference"). It may be difficult to track FDA's interpretation of the law concerning veterinarians, but it is certain that the agency's interpretation about its authority over physicians is inconsistent with the ruling made by the Seventh Circuit.

In addition, an agency's interpretation of the statutes it administers is entitled to deference only if that interpretation is rational. *Young v. Community Nutrition Institute*, ___ U.S. ___, 106 S. Ct. 2360, 2364-65 (1986); *Chemical Manufacturers Assn. v. Natural Resources Defense Council*, 470 U.S. 116, 125 (1985). The director of FDA's Center for Veterinary Medicine has described the irrationality of FDA's policy. *He stated that there are disease entities for which there are not FDA-approved drugs and that to treat these diseases a veterinarian must practice medicine in violation of the law as FDA interprets it.* Appellees' S.A. at 65-68. Dr. Guest acknowledged that FDA's interpretation of the Act did not coincide with the ethical practice of veterinary medicine. Appellees' S.A. at 69-71. A governmental scheme of regulation that requires a profession to engage in criminal acts to preserve the health of the public and patients cannot be considered rational. Such an interpretation of the Act is entitled to no deference.

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[32] In 1973, FDA agreed that a veterinarian *could* in the course of his practice ship unapproved drugs in interstate commerce and not be the subject of "new drug" charges. *United States v. Cockerill*, 366 F. Supp. 856, 857-858 (S.D. Ill. 1973).

V. THE SEVENTH CIRCUIT'S OPINION MISREADS SEVERAL FUNDAMENTAL FACTS AND CIRCUMSTANCES

A. FDA's Extra-Label Use Policy Does Not Immunize Veterinarians From The Risk Of FDA Enforcement Actions

The Seventh Circuit concluded that FDA could have prosecuted "thousands of individual veterinarians" for using "new drugs" that they compounded. That is no doubt why the court found some latitude in FDA's extra-label use policy -- set forth in Compliance Policy Guide 7125.06 (Nov. 1, 1986) -- saying that it is a "non-enforcement policy related to the one sustained in *Heckler v. Chaney*." App. 8a. The *Chaney* decision recognized that FDA did not have to exercise its enforcement authority to prevent unapproved drugs from being used for unapproved purposes, that is for executions. However, the latitude of the extra-label use policy is an illusion: the policy is FDA's statement that it will prosecute any veterinarian it chooses when drugs are used except as FDA prescribes. Some veterinarians are identified as less likely to be prosecuted, but as the commissioner has said, any veterinarian who exercises judgment beyond the FDA-approved labeling "does so at his own peril." Appellees' S.A. at 74. This "non-enforcement policy" is nothing more than a malpractice Pandora's box. If the use of a drug for a purpose not approved by FDA is illegal, veterinarians will find themselves at an increased risk that they will be liable for both punitive and compensatory damages for any injuries that occur, even if their treatments are ethically correct. *See, e.g., Stanton v. Astra Pharmaceutical Products*, 718 F.2d 553, 563-564 (3d Cir. 1983) (violation of government safety regulation constitutes negligence *per se*).

The record in this case establishes that the ethical practice of veterinary medicine and FDA's scheme of regulation as approved by the Seventh Circuit are not coextensive. The extra-label use policy does nothing to relieve this, except to invite veterinarians with sufficient daring to risk fines and imprisonment to practice medicine properly.

B. Veterinarians Are Properly Trained To Compound Drugs

The foremost concerns of veterinarians are the health of consumers of animals used as food sources, and of the animals themselves.[33] Compounding of medicines is absolutely necessary to the correct practice of veterinary medicine.[34] Veterinary medical schools and the veterinarians' own continuing education provide extensive training in chemistry and pharmacology to enable them to compound and prescribe effectively.[35] Veterinarians, to do their task properly, must be able to use drugs in a manner consistent with the health of the animals and, in the case of food-producing animals, the consuming public's health.[36] None of the foregoing was contested by FDA.

C. FDA's Action Is Inconsistent With The Proper Practice Of Veterinary Medicine

FDA's director of veterinary medicine *admits* that FDA's interpretation of the Act is inconsistent with the ethical practice of veterinary medicine. Appellees' S.A. at 69-71. Moreover, it is also inconsistent with FDA's own application of the Act with respect to finished form veterinary drugs. In contrast to FDA's desire to regulate veterinarians, FDA has admitted that approximately 90 percent of finished form veterinary drugs on the market, all considered "new," are not FDA-approved.[37]

Bulk drugs provide veterinarians with the necessary flexibility to assure the health of the animals they treat.[38] It makes

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[33] Clack Statement at ¶3, Appellees' S.A. at 22; Crouch Statement at ¶4, Appellees' S.A. at 27-28; Skiles Statement at ¶8, Appellees' S.A. at 32; VanDamme Statement at ¶8, Appellees's S.A. at 38-39.

[34] *See, e.g.*, Clack Statement at ¶4, Appellees' S.A. at 22-23; Crouch Statement at ¶7, Appellees' S.A. at 29.

[35] Crouch Statement at ¶4, Appellees' S.A. at 27-28.

[36] *See, e.g.*, Clack Statement at ¶¶3-5, Appellees' S.A. at 22-23.

[37] *The Regulation of Animal Drugs by the Food and Drug Administration: Hearings Before the Subcomm. on Intergovernmental Relations and Human Resources of the House Comm. on Government Operations*, 99th Cong., 1st Sess. 29 (1985).

[38] Clack Statement at ¶9, Appellees' S.A. at 25; Skiles Statement at ¶7, Appellees' S.A. at 32.

no sense to try to use finished form drugs to compound medications because the finished form drug must be altered to fit the needs of the situation and patient, the finished form drug contains unnecessary ingredients, and quality pure bulk drugs are available.[39] In some instances, bulk drugs are the *only* available treatment, and failure to use them would result in the death of many animals.[40] Again, none of the foregoing was contested by FDA.

D. Veterinarians Are Subject To Legal Scrutiny

The Seventh Circuit dealt skeptically with the controls that are available to govern the conduct of veterinarians, expressing the belief that civil liability and professional discipline were not adequate. App. 6a. Whether veterinarians' pockets are "deeper" than those of pharmaceutical companies and whether veterinarians and physicians are sufficiently accountable to their states under the criminal codes and the licensing authorities should not determine how to read the FDC Act.

But neither petitioner nor the individual veterinarians claim any blanket immunity under the law. This case does not involve the question of whether veterinarians can become drug manufacturers without prior FDA approval. Veterinarians who act outside the scope of their practices have the standing of laymen, *cf. United States v. Moore*, 423 U.S. 122 (1975), and as such have no right to receive or compound any bulk materials that a layman could not obtain. Further, should a veterinarian misuse any medicines and harm the animals or cause residues in the food, then all recognize that a veterinarian could be prosecuted under the FDC Act for adulterating food.[41] Also, the veterinarian would be subject to disciplinary action by the state licensing authorities and the profession. *See, e.g.*, Ill. Ann. Stat. ch. 111, ¶7025 (1986).

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[39] *Id.*

[40] Westlake Statement at ¶6, Appellees' S.A. at 40-41.

[41] 21 U.S.C. §342; Compliance Policy Guide 7125.06, "Extra-Label Use of New Animal Drugs in Food-Producing Animals" (Nov. 1, 1986).

VI. CONCLUSION

The activity under consideration in this case is the compounding and prescribing of medicines by veterinarians. Drug therapy is essential to treatment regimens, in animals as well as man. Congress wisely never intended to give FDA the destructive control it seeks; veterinarians must prescribe for patients, not federal regulators. The district court correctly interpreted the law to deny FDA the ability to assert prior approval over veterinarians' use of each and every medicine for each patient and condition. App. 22a.

For reasons that do not appear in the record, the Seventh Circuit found that veterinarians and others who administer medicines are not able to calculate patient treatment regimens as well as FDA; the court cited the example of diethylstilbestrol. App. 6a. Nothing in our system, including FDA, can guarantee perfect safety. On the other hand, the record in this case abundantly establishes that a quick and easy way to assure catastrophe is to insert government bureaucracy into every individual patient treatment decision. The legislative history of the FDC Act recognizes the need for latitude when professionals treat their patients, and establishes the exemption which the Seventh Circuit denied.

For all of these reasons, this Court should exercise its discretion to review the Seventh Circuit's decision in this case because it decides an important question of federal law which has not been, but because of its importance should be, settled by this Court.

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In the
UNITED STATES COURT OF APPEALS
For the Seventh Circuit

No. 88-1233

United States of America,

Plaintiff-Appellant,

v.

9/1 KG. CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE,

Defendants-Appellees.

Appeal from the United States District Court
for the Central District of Illinois, Springfield Division.
No. 86-3201-Richard Mills, *Judge*.

ARGUED JUNE 9, 1988–DECIDED JULY 27, 1988

Before EASTERBROOK and MANION, *Circuit Judges*, and ESCHBACH, *Senior Circuit Judge*.

EASTERBROOK, *Circuit Judge*. No one may sell a new animal drug, or feed containing a new animal drug, without the approval of the Food and Drug Administration. 21 U.S.C. §360b. Obtaining approval takes a long time and costs a lot of money, for the FDA requires thorough experimentation to determine both the drug's effects on animals and whether its residues persist in the animals and enter the food chain. A drug that leaves potentially-dangerous residues will not be approved. Scientists' ability to determine the long-range effects of many chemical substances is limited; that lack of knowledge, coupled with the FDA's cautious approach, means that few new animal drugs have been approved. We must take it as given that for significant diseases there are no

effective FDA-approved drugs. Acute mastitis, which may decimate a herd of dairy cattle in short order, cannot be treated with approved new animal drugs; neither can shipping fever and salmonella in feedlot cattle. The FDA has not approved any general anesthetic for field use in surgery on food animals. For the principal diseases of non-food animals, such as mink and fox, there are few, if any, approved remedies.

Many veterinarians find this state of affairs deplorable. Because they cannot buy in finished form the drugs they think they should be able to use, they have elected to make their own. They purchase the active ingredients, mix them in the proportions they think best, and administer their concoctions as professional judgment dictates. The veterinarians do not sell the drugs, so the FDA's usual methods of control do not come into play. The FDA looked the other way for decades. Cf. *Heckler v. Chaney*, 470 U.S. 821 (1985). Recently, however, the FDA became concerned about the end-run around its approval process-perhaps because the practice has become widespread-and decided to put a stop to it. The FDA might have prosecuted thousands of individual veterinarians for administering unsafe drugs (any new animal drug is deemed unsafe unless approved by the FDA, 21 U.S.C. §360b(a)), but the agency thought it easier to cut off the veterinarians' supply of active ingredients. This case is the result.

The FDA decided to intercept the drugs in the hands of the middleman: in this case Schuyler Laboratories, Inc., which purchased unblended ingredients from their manufacturer and resold them, still in bulk, to veterinarians. Such a middleman does not manufacture drugs and therefore ordinarily does not need to seek the FDA's approval via new animal drug applications. (Things may be different when the drug is an antibiotic listed in 21 U.S.C. §321(w)(3); we shall not have to decide.) In July 1986 the FDA swooped down on Schuyler and seized every container of drugs on the premises. It carted off 52 lots and filed a complaint seeking their forfeiture as "misbranded" drugs. See 21 U.S.C. §334(a)(1). (How the caption of this case came to be as it is baffles us.) The bulk drugs were "misbranded", according to the FDA, as a result of this requirement in 21 U.S.C. §352:

> A drug or device shall be deemed to be misbranded-
>
> . . .
>
> (f)Unless its labeling bears (1) adequate directions for use; . . . *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary [of Health and Human Services] shall promulgate regulations exempting such drug or device from such requirement.

The labels of the containers on Schuyler's premises gave the name of the drug and its manufacturer, but no directions for use. It would be difficult to create labels with such directions, because bulk drugs are to be mixed or otherwise compounded rather than used in their current form. The drugs are therefore "misbranded" unless Schuyler can take advantage of the proviso.

> The regulation implementing the proviso states:
>
> A drug in a bulk package, except tablets, capsules, or other dosage unit forms, intended for processing, repacking, or use in the manufacture of another drug shall be exempt from §502(f)(1) [21 U.S.C. §352(f)(1)] of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking"; . . . . But the exemption shall not apply to a substance intended for use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:
>
> (a) An approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder by persons named in the application . . . .

21 C.F.R. §201.122. Schuyler's bulk drugs do not qualify under this regulation as written, because although they are "intended for use in manufacture" (etc.) Schuyler has not offered to show that an approved new animal drug application covers the substance that will ensue. Schuyler argues that the qualification in the regulation starting with "But the exemption shall not apply . . ." is unlawful because not "necessary for the protection of the public

health" within the meaning of §352(f). In other words, Schuyler wants the benefits of the first sentence of §201.122 without the burden of satisfying the remainder of the regulation. Everything after the first sentence, Schuyler believes, must be discarded; the bulk drugs would come within the remaining language.

The district court agreed with Schuyler and ordered the FDA to return the drugs. 674 F. Supp. 1344 (C.D. Ill. 1987). Accord, *United States v. Algon Chemical Inc.*, No. 87-1820 (D.N.J. Apr. 12, 1988). As it saw things, the limits on the permission to sell unlabeled bulk drugs are neither necessary nor prudent for three reasons: Congress wanted to leave medical professionals free to practice as their judgment required; veterinarians are not regulated in compounding drugs, implying liberty to obtain drugs to compound; and the middleman cannot know whether its customer has the necessary approval. We stayed the district court's order pending appeal.

The statute treats drugs without directions for use as presumptively misbranded. Schuyler bears the burden of establishing its entitlement to treatment under the exception. *United States v. An Article of Device "Toftness Radiation Detector"*, 731 F.2d 1253, 1260-62 (7th Cir. 1984). Whether there is a safe harbor for Schuyler to seek depends in the first instance on the FDA's judgment about the conditions necessary to protect the public health. The phrase "necessary for the protection of the public health" in §352(f), like the phrase "public interest, convenience, and necessity" in other regulatory statutes, delegates authority to an agency. See *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 321 (1981); *Colorado v. United States*, 271 U.S. 153, 168-69 (1926); *Black v. ICC*, 737 F.2d 643, 650 (7th Cir. 1984). It requires the agency to make a judgment about where the public interest lies. Courts defer to the FDA when it construes its governing statutes. E.g., *Young v. Community Nutrition Institute*, 476 U.S. 974 (1986); cf. *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.* 467 U.S. 837 (1984); *Continental Air Lines, Inc. v. Department of Transportation*, 843 F.2d 1444, 1448-54 (D.C. Cir. 1988). The FDA's task was not, however, to "construe" a statute. It was to make a judgment about a medi-

cal subject. Someone must draw on knowledge about risks and needs and decide how much risk is too much; that someone is the Executive Branch of the government. "[T]he first question in determining the deference appropriate to the agency[]. . . is whether Congress has transferred discretion to the agency. If the legislation either calls for the agency's decision or contains no disposition of the subject, then the agency has been deputized to make a rule, and its decision should be respected." *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 411 (7th Cir. 1987). So Schuyler is fighting a doubly-uphill battle: it bears the burden of establishing an exception to the labeling requirement, which it can get only by showing that the FDA's views about the needs of public health are arbitrary and capricious.

The district court thought that they are because "it was not the purpose of the Act to involve the agency in the practice of the healing arts." 674 F. Supp. at 1348. If not that, however, what *does* the statute do? Congress gave the FDA comprehensive powers to license the manufacture of drugs and limit their sales. To regulate drugs is to be "involved" in the "practice of the healing arts." True, the Senate report that accompanied the original statute in 1935 said that the bill was "not intended as a medical practices act and [would] not interfere with the practice of the healing art[s]", S. Rep. No. 361, 74th Cong. 1st Sess. 3 (1935), but the statute has undergone much amendment since then, including a complete over-haul in 1962. Phrases such as the one in the 1935 Senate report-not repeated in 1962-never meant more than that medical licensure and discipline would continue to be the states' business; states, not the FDA, would decide whether (for example) physicians had selected wisely from among methods of treatment. The full quotation, redacted by Schuyler and the district court, makes the point: the statute is "not intended as a medical practices act and [would] not interfere with the practice of the healing art *by chiropractors and others*". So states set medical qualifications, and practitioners who do not use drugs (i.e., chiropractors) may go on as before. Nothing in the history or structure of the Act permits drugs deemed ineffective or dangerous by the FDA to be available for use. *United States v. Rutherford*, 442 U.S. 544 (1979).

We do not question the good will of physicians, veterinarians, and other medical professionals. Still, no individual veterinarian will possess complete knowledge of the efficacy of a novel drug compound-let alone of its persistence in the food chain. The testing required to obtain a new animal drug approval is costly and extended precisely because information is so difficult to come by. Testing must isolate the effects of the drug in question from all other environmental influences, then follow the animals for years (even generations of animals) to identify the consequences. This requires data from large populations of animals and the application of powerful statistical techniques. No solitary medical professional can carry out this program of knowledge acquisition for even one drug, let alone for the bevy of drugs a veterinarian may choose to compound. All the good judgment in the world is useless when we lack essential knowledge.

Schuyler (and the veterinary groups supporting it as *amici curiae*) responds that if veterinarians err in compounding and administering novel drugs, they will be subject to professional discipline, and the sellers of the afflicted animals to tort liability. All very well, *if* the sellers and veterinarians had the wealth to pay what could turn out to be staggering tort judgments, and *if* it should prove possible to trace cancers developing 20 years hence to residues in particular animals treated by particular veterinarians. But the sellers and veterinarians do not have the wealth needed to compensate all potential victims fully, and it would be difficult-more likely impossible-to attribute loss to a particular source many years after the fact. One need only think of the complexities of DES litigation to see a shadow of what would happen if courts had to trace drugs back through the food chain to find their sources. Even though DES was administered directly to patients, it is often impossible to identify the seller of the particular drug, and identified sellers may be out of business.

Some of the bulk drugs seized from Schuyler pose risks. Schuyler was holding for sale dimatridazole and nitrofurans, both of which have been found to cause cancer in animals and inferentially to pose a risk to humans. The FDA has withdrawn existing approvals to sell finished drugs containing dimatridazole, 52 Fed.

Reg. 25312 (1987), and has proposed to withdraw approvals for finished nitrofuran products, 49 Fed. Reg. 34965 (1984). Schuyler nonetheless believes that veterinarians (and other medical professionals) should be free to compound drugs containing these ingredients, in their sole judgment. Reasonable persons could think it appropriate to rely on tort law and professional discipline, despite the difficulties we have outlined, to assure the safety of drugs used in food animals (and for other purposes), but Congress and the FDA have reached a different conclusion.

The district court believed, however, that Congress made an earnest of its desire to steer clear of regulating medical judgment by excluding veterinarians from several features of the regulatory system. For example, although the manufacture of drugs is tightly controlled, Congress exempted from these controls practitioners who "prescribe or administer drugs. . .and who manufacture, prepare propagate, compound, or process drugs. . . solely for use in the course of their professional practice." 21 U.S.C. §360(g)(2). The district court reasoned: "It makes no sense for Congress to grant this exemption. . .if it then takes away the very drugs that would be compounded." 674 F. Supp. at 1349.

This conclusion depends on a suppressed assumption: that §360(g)(2) covers *all* drugs, rather than only drugs made from components that lawfully may be obtained and compounded. There isn't any support for the assumption. The straightforward reading of this language is the one the FDA gives it: "[V]eterinarians may use in the compounding of prescriptions for their private practice whatever bulk drugs or other pharmaceuticals they may lawfully purchase." FDA Compliance Policy Guide §7125.10 (July 13, 1976). It does not guarantee that any particular drug will be available lawfully. *Rutherford* shows as much in holding that physicians may not obtain laetrile for administration to dying patients, even on the assumption that the drug is harmless and the prescription (or compounding) private. The FDA treats §360(g)(2) as allowing veterinarians to "prepare, propagate, compound, or process drugs *from ingredients they lawfully acquire*", and the added words are no more than those implied in every statute. Schuyler does not say that §360(g)(2) allows veterinarians to steal

drugs in order to compound them, or to import drugs that are otherwise banned; no more does it allow them to obtain drugs that are otherwise mislabeled. To the extent there is any doubt, we accept the FDA's reading of its own statute. *Young v. Community Nutrition Institute*. Medical professionals may use their privilege under §360(g)(2) to mix drugs available outside the new drug application system-"grandfathered" drugs available in 1935 and recognized then as safe and effective. They also may further compound drugs that have been approved by the FDA, to at least a limited extent. This "extra-label use" is governed by a non-enforcement policy related to the one sustained in *Heckler v. Chaney*. If the need is great and the risk is small, the FDA will not contend that re-mixing approved drugs, or using them in a way other than per directions on the label, causes their "adulteration" under the act. FDA Compliance Policy Guide §7125.06 (Nov. 1, 1986).

The district court's final objection to §201.122 was that "it shifts to the claimant an unreasonable burden to show that the exemption applies. . . . Because of the nature of bulk drugs. . ., it is impossible to tell, at this stage whether the finished product will be a new drug since there is no finished product yet. Thus, the FDA would force the claimant to produce proof which is non-existent in order to invoke exemption. This result is unreasonable." 674 F. Supp. at 1349. It is not, however, "impossible" to tell what will become of bulk drugs. The seller need only ask the buyer what use lies in store. If the answer discloses impending compounding that would produce a "new animal drug", the seller must ask the buyer to display a filed or granted new drug application. That inquiry would not detain Schuyler, because it is stipulated that (a) all of its sales are to veterinarians, and (b) not a single veterinarian in the United States holds an approved new animal drug application for any drug, and none has such an application on file. More: The Federal Register contains a list of all filed and approved new animal drug applications, so Schuyler could check through that source as well. The task of inquiry set by the regulation, far from being "impossible", turns out to be easy. The easy answer reveals that Schuyler can never *satisfy* this aspect of the regulation when

individual veterinarians are the buyers, but this is different from showing that it is impossible to acquire essential information.

The effect of §352(f) and §201.122 is that ingredients that can be used to produce "new" drugs may be sold only to firms that hold approved (or have filed) new animal drug applications. The FDA carefully scrutinizes the activities of these manufacturers. This is a sensible result in light of the structure of the statute.

The statute itself is not universally praised. As Schuyler points out, the FDA has not approved drugs adequate to deal with significant animal diseases. Careful scholars have concluded that the FDA is overly cautious, deprecating benefits and overestimating risks in a way that keeps beneficial drugs off the market, while unduly deferring the introduction of other drugs and raising the cost (and, ironically, the riskiness) of drugs finally made available. E.g., David Leo Weimer, *Safe-And Available-Drugs*, in **Instead of Regulation: Alternatives to Federal Regulatory Agencies** 239 (Robert W. Poole, Jr., ed. 1982); Sam Peltzman, *The Health Effects of Mandatory Prescriptions*, 30 J.L. & Econ. 207 (1987). The certification process hampers small firms and may produce a concentrated industry with higher prices still. Cf. Peter Temin, **The Role of Regulation and Technology in the Creation of the Modern Pharmaceutical Firm** (1978). It may be no accident that the trade associations of the large drug houses have appeared in this case as *amici curiae* in support of the FDA. Perhaps the individual judgment of medical professionals (including the pharmaceutical houses that do not recklessly expose their treasuries to depletion in tort litigation) does better than bureaucratic judgment despite the difficulties we have mentioned. Subjects such as these are for Congress and the FDA to consider. Judges' role is to decipher and enforce the existing scheme, whatever they think of its wisdom.

The statute essentially forbids the sale, in any form, of drugs formulated or put to new uses after 1935, without the approval of the FDA. Schuyler, which bears the burden of proof, has not offered to show that the FDA has approved the formulations and uses its customers would make of its bulk drugs. The statutory "hook" for implementing the prohibition is the labeling rule. The 52 lots of bulk drugs seized from Schuyler are mislabeled under

§352(f), and Schuyler does not come within the regulatory exemption. The drugs are forfeit.

REVERSED

UNITED STATES of America, Plaintiff,

v.

9/1 KG CONTAINERS, More or Less of an ARTICLE OF DRUG FOR VETERINARY USE, et al., Defendants.

No. 86-3201.

United States District Court,
C.D. Illinois,
Springfield Division.

Dec. 8, 1987.

Government sought condemnation of bulk animal drugs for misbranding and adulteration. Seller of bulk drugs to veterinarian moved for summary judgment. The District Court, Mills, J., held that: (1) bulk drug exemption from labeling requirement was out of harmony with statutory intent to extent that it did not apply to seller of bulk drugs unless seller could show that finished product was not new drug or that new animal drug application was secured, and (2) bulk animal drugs were not new animal drugs and were not dangerous or adulterated.

Motion granted.

1. Drugs and Narcotics

Government claiming that bulk animal drugs were misbranded had burden to show by preponderance of evidence that seized drugs were intended for use in animals, that they did not bear adequate directions for use, and that drugs were held for sale after shipment in interstate commerce. Federal Food, Drug, and Cosmetic Act, § 502(f)(1), as amended, 21 U.S.C.A. § 352(f)(1).

2. Drugs and Narcotics

Regulation exempting bulk drugs from labeling requirement, unless use of bulk drug would result in finished product which was

new drug, was not in harmony with letter and intent of labeling requirement statute to extent that seller of bulk drugs to veterinarians would not enjoy exemption unless finished product was not new drug or new drug application was approved; extent to which Food and Drug Administration intended to involve itself in healing arts was inconsistent and not in harmony with statutory intent. Federal Food, Drug, and Cosmetic Act, §§ 201(w)(3), 501(a)(5), 502(f)(1), 512(a)(1), as amended, 21 U.S.C.A. §§ 321(w)(3), 351(a)(5), 352(f)(1), 360b(a)(1).

3. Drugs and Narcotics

Regulation exempting bulk drugs from labeling requirement, unless use of bulk drug would result in finished product which was new drug, unreasonably shifted burden to seller of bulk drugs to veterinarians to show that finished product in which bulk drug was used was not new drug or that new animal drug application had been approved; bulk drugs were compounded with other drugs and substances to make finished product; it was impossible to tell whether finished product would be new drug; and seller could not secure application without idea of what drug would be produced. Federal Food, Drug, and Cosmetic Act, § 502(f)(1), as amended, 21 U.S.C.A. § 352(f)(1).

4. Drugs and Narcotics

Remedy for regulation, which exempted bulk drugs from labeling requirement and which was out of harmony with letter and intent of labeling requirement, was to read regulation as consistent with statute to extent possible; thus, regulation exempted bulk drugs from general requirement, but did not require seller of bulk drugs to veterinarians to show that finished product in which bulk drug was used was not new drug or that new animal drug application was approved. Federal Food, Drug, and Cosmetic Act, § 502(f)(1), as amended, 21 U.S.C.A. § 352(f)(1).

5. Drugs and Narcotics

Bulk animal drugs consisting of ampicillin trihydrate, amoxicillin trihydrate, tetracycline HCL, streptomycin sulfate, and penicillin V potassium were not in finished dosage form, were not

intended for use in animals in present form, were not "new animal drugs," and were not unsafe or adulterated. Federal Food, Drug, and Cosmetic Act §§ 201(w)(3), 501(a)(5), 502(f)(1), 512(a)(1), as amended, 21 U.S.C.A. §§ 321(w)(3), 351(a)(5), 352(f)(1), 360b(a)(1).

See publication Words and Phrases for other judicial constructions and definitions.

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OPINION

MILLS, District Judge:

In this cause, the Government seeks the condemnation of bulk animal drugs pursuant to 21 U.S.C. § 334.[1] As this is a case of first impression, we proceed with very little in the way of case law to guide us.

The Government alleges that the drugs do not have adequate directions for use and are, therefore, misbranded. Additionally, the Government claims that five of the lots are subject to condemnation because they have not been approved by the Food & Drug Administration (FDA). The claimant, Schuyler Laboratories (Schuyler), argues that the seized articles of drug are exempt from the labeling requirements of the Food, Drug, and Cosmetic Act (Act).

The parties have filed cross-motions for summary judgment pursuant to Fed.R. Civ.P. 56. Rule 56 authorizes summary judgment where no genuine issue as to any material fact exists, and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

This is such a case.

Summary judgment for claimant.

I. Facts

The facts are undisputed. The complaint, filed July 3, 1986, alleges that the Defendant drugs are misbranded under the

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[1] The section states in pertinent part:

> Any article of . . . drug . . . that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of sections 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States . . . within the jurisdiction of which the article is found . . . .

21 U.S.C. § 334(a)(1). All section references herein are to sections of the Act as found in the U.S. Code.

provisions of 21 U.S.C. § 352(f)(1),[2] in that their labels do not bear "adequate directions for use."[3] The complaint further alleges that certain of the drugs are unapproved new animal drugs within the meaning of 21 U.S.C. § 321(w)(3),[4] and, therefore, are adulterated under 21 U.S.C. §§ 360b(a)(1)[5] and 351(a)(5).[6]

On July 9, 1986, the United States Marshal seized approximately 52 lots of drugs at the Schuyler facility in Rushville, Illinois. Schuyler filed a claim for the drugs on July 18, 1986.

Schuyler purchases bulk drugs (active drug ingredients that require further processing before use) for repacking and sale directly and exclusively to veterinarians. Some of the seized articles were in the original containers in which the drugs were

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[2] The section provides in pertinent part: "A drug or device shall be deemed to be misbranded . . . [u]nless its labeling bears (1) adequate directions for use . . ." See endnote 3 for definition of "adequate directions for use."

[3] 21 C.F.R. § 201.5 defines "adequate directions for use" as "directions under which a layman can use a drug safely and for the purposes for which it is intended."

[4] The section states in pertinent part:

> The term "new animal drug" means any drug intended for use of animals other than man, including any drug intended for use in animal feed but not including such animal feed . . . which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug . . . .

21 U.S.C. § 321(w)(3).

[5] The section states in pertinent part:

> A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 351(a)(5) and section 342(a)(2)(D) of this title unless-
>
> (a) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug . . . .

21 U.S.C. § 360b(a)(1).

[6] "A drug or device shall be deemed to be adulterated . . . if it is a new animal drug which is unsafe within the meaning of section 360(b) of this title . . . ." 21 U.S.C. § 351(a)(5).

shipped to Schuyler. The labeling of these products bears shipping information, such as the name and place of business of the manufacturer, packer, or distributor, and the identity of the bulk drug substance. The remaining articles seized had been repacked by Schuyler and bear labels that contain the name "Schuyler Laboratories" and state "for manufacturing, processing, or repacking," and contain the name of the drug. The seized articles are not accompanied by labeling that bears directions for use.

II. Analysis

A. Labeling under § 352(f)(1)

Under 21 U.S.C. § 352(f)(1),

> [a] drug or device shall be deemed to be misbranded--
> ... Unless its labeling bears (1) adequate directions for use; ... *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary *shall* promulgate regulations exempting such drug or device from such requirement. (emphasis supplied)

In response to the *mandatory* proviso of the above quoted section, the Secretary promulgated the following exemption for bulk drugs:

> A drug in a bulk package, except tablets, capsules, or other dosage forms, intended for processing, repacking, or use in the manufacture of another drug shall be exempt from § 502(f)(1) [21 U.S.C. § 352(f)(1)] of the Act if its label bears the statement "Caution: For manufacturing, processing, or repacking" .... But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug ....

21 C.F.R. § 201.122 (1987).

It is the Government's contention that the limitation on the exemption ("But the exemption shall not apply ...") works to take these bulk drugs out of the exemption because the finished articles

form new animal drugs. On the other hand, Schuyler contends that the bulk drugs are exempt and the limitation on the exemption does not come into play because the compounded drugs are not new animal drugs.

1. *The Burden of Proof*

[1]The burden of proof falls on the Government to show by a preponderance of the evidence that: (1) the seized drugs are intended for use in animals; (2) that they do not bear adequate directions for use; and (3) that the drugs were held for sale after shipment in interstate commerce. *See United States v. An Article of Device: "Toftness Radiation Detector,"* 731 F.2d 1253, 1261 (7th Cir.), *cert. denied*, 469 U.S. 882, 105 S. Ct. 249, 83 L.Ed.2d 186 (1984). Since these facts have been admitted by claimant, the Government has carried its burden. Thus, the seized drugs are misbranded unless they fall within one of the exemptions from the requirement. Claimants contend that the drugs fall within the bulk drug exemption of 21 C.F.R. § 201.122 (quoted above).

There is a disagreement among the parties as to whose burden it is to show the applicability or nonapplicability of the exemption. To resolve this issue we are guided by *Toftness*, wherein the Court of Appeals, addressing the misbranding of a prescription device under § 352(f)(1), determined that one claiming an exemption under the misbranding regulations bears the burden of showing its applicability. The Court came to this conclusion after analysis of the statute's structure and application of the general rule that a party claiming entitlement to a statutory exemption bears the burden of proving the entitlement. *See United States v. First City Nat'l Bank*, 386 U.S. 361, 366, 87 S.Ct. 1088, 1092, 18 L.Ed.2d 151 (1967). The *Toftness* court stated:

> [T]he FDA promulgated the regulations . . . and those regulations make prescription devices one of several exemptions to the more general labeling requirements. No purpose justifying this odd structure occurs to us other than the purpose of shifting the burden of proof. By treating the large category of prescription devices under an exemption to the more general requirements,

> the FDA appears to have wanted to make its task somewhat easier by placing on claimants the burden of proving that their device is safe and is actually effective for its intended purposes.
>
> Although this regulatory arrangement may seem strange insofar as it makes prescription devices presumptively misbranded, the [regulatory scheme] is not contrary to either the letter or intent of the statute.

Toftness, 731 F.2d at 1261.

Thus, according to *Toftness*, unless the exemption is contrary to either the letter or intent of the statute, Schuyler must bear the burden of showing the applicability of the exemption.

2. ***Applicability of the Bulk Drug Regulation***

It is axiomatic that for regulations to be valid they "must be consistent with the statute under which they are promulgated." *United States v. Larionoff*, 431 U.S. 864, 873, 97 S.Ct. 2150, 2156, 53 L.Ed. 2d 48 (1977). In *Manhattan General Equip. Co. v. Commissioner*, 297 U.S. 129, 56 S.Ct. 397, 80 L.Ed. 528 (1936), the Court stated: "The power of an administrative officer or board to administer a federal statute and to prescribe rules and regulations to that end is . . . [only] the power to adopt regulations to carry into effect the will of Congress as expressed by statute. A regulation which does not do this, but operates to create a rule out of harmony with the statute, is a mere nullity." *Id.* at 134, 56 S.Ct. at 400, *quoted in Larionoff*, 431 U.S. at 873 n. 12, 97 S.Ct. at 2156 n.12.

In the instant case, the regulation states that bulk drugs such as those at issue are exempt from the § 352(f)(1) labeling requirements *unless* the bulk drug's use will result in a finished product which is a "new drug." However, under the regulation this "new drug" limitation can be avoided if an approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder-in this case the veterinarian.

Thus, the question for this Court is whether the bulk drug exemption regulation is in harmony with the letter and intent of the

statute under which the regulation was enacted. For the reasons given below, the Court finds that the regulation is not in harmony with the legislation.

a. *The Legislative Scheme Generally*

[2] Generally, Congress has shown a reluctance to interfere with the healing arts, of which veterinary medicine is obviously one. Specifically, the legislative history of the Food, Drug, and Cosmetic Act does not support the authority of FDA to meddle in the field of drug compounding done within the scope of the professional practice of medicine-be it veterinary or otherwise.

When the Act became law in 1938, it was clear to the legislators that it was not the purpose of the Act to involve the agency in the practice of healing arts. The committee reports made clear the bill was "not intended as a medical practices act and [would] not interfere with the practice of the healing art[s] . . . ." S.Rep. No. 361, 74th Cong., 1st Sess. 3 (1935), *quoted in Chaney v. Heckler*, 718 F.2d 1174, 1179 n. 13 (D.C.Cir.1983), *rev'd on other grounds*, 470 U.S. 821, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985). The *Chaney* court further stated that "the legislative history makes clear that Congress did not want to limit a physician's ability to treat his patients." *Chaney*, 718 F.2d at 1179 n. 13. As a former chief counsel to the FDA has stated:

> The legislative history of the . . . Act of 1938 is replete with statements that the statute was not intended to regulate the practice of medicine. The man who guided the legislation through the Congress, Senator Royal Copeland, was a physician, and was undoubtedly concerned about interfering with his profession . . . . Through the six years of legislative history the proposed legislation contained the affirmative requirement that every drug must bear adequate directions for use. Not only does the legislative history fail to show a Congressional intent that this be used to restrict the conditions for which physicians might prescribe drugs, but it flatly contradicts any such interpretation. In enacting the

> 1938 Act Congress clearly intended to avoid impinging on the practice of medicine.

Hutt, Regulation of the Practice of Medicine Under the Pure Food & Drug Laws, 33 A. of Food & Drug Officials Q.Bull. 3, 7 & 9 (1969).

In 1962, the Drug Amendments Act, Pub. L. No. 87-781, 76 Stat. 781 (1962), greatly enhanced the FDA's regulation responsibilities. However, some explicit exclusions from that expanded authority uphold the original intent of the Act-that Congress nor the FDA should involve itself in the practice of the healing arts. For example, 21 U.S.C. § 374(a)(2) gave the FDA vast inspection powers with respect to prescription drugs. However, § 374(a)(2)(B) specifically exempted licensed practitioners who prescribe or administer drugs within the scope of their profession. Further, in § 360(a)(1) & (b), Congress defined "manufacture, preparation, propagation, compounding, or processing" for purposes of requiring the registration with the FDA of persons engaging in such activities. Yet, Congress specifically exempted from such registration licensed practitioners who "prescribe or administer drugs . . . and who manufacture, prepare, propagate, compound, or process drugs . . . solely for use in the course of their professional practice." 21 U.S.C. § 360(g)(2). This exemption is of particular interest as we are now concerned with the compounding of drugs by persons professionally licensed to do so. It seems peculiar that Congress would see fit to sanction such an exemption on the one hand, and on the other, permit the FDA to regulate labeling in the way it attempts to here. It makes no sense for Congress to grant this exemption, under § 360(a)(1), if it then takes away the very drugs that would be compounded.

Throughout the Act's history, Congress has shown a consistent pattern of staying out of the regulation of the healing arts. The extent to which the FDA attempts to involve itself in the healing arts here is clearly inconsistent and out of harmony with the statute's intent as manifested by Congress.

b. ***Unreasonableness of the Burden of Proof***

[3] The second reason the Court finds the regulation not to be in harmony with the statute is that it shifts to the claimant an

unreasonable burden to show that the exemption applies. Under the Government's regulatory scheme, for the exemption to apply, the claimant must show one of two things: (1) that the finished product in which the bulk drug is used is not a new drug; or (2) that if it is a new drug, a new animal drug application has been secured.

In the previously discussed case of *Toftness*, the Seventh Circuit expressly sanctioned the structuring of a regulation to shift the burden of an exemption's application to the claimant in a misbranding action. However, one of the grounds upon which the Court based its decision was the fact that the claimant was in a better position to come forward with the evidence which could show applicability of the exemption. In other words, claimant there was in a better position to show that the prescription device worked safely and effectively.[7]

Here, that is not the case. In fact, not only can the claimant not come forward with such evidence, but neither can the Government. Because of the nature of bulk drugs (drugs compounded with other drugs and substances to make a finished product), it is impossible to tell, at this stage, whether the finished product will be a new drug since there is no finished product yet. Thus, the FDA would force the claimant to produce proof which is nonexistent in order to invoke the exemption. This result is unreasonable.

Equally unreasonable is the claimant's option, under exemption regulation, of showing that if a new drug is being produced that a new animal drug application has been secured. Because the claimant has no idea what drug will be produced, he is in no position to secure an application. Second, the expectation that veterinarians should secure a new animal drug application ignores

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[7] The Court stated as its holding on the issue: Because the [claimants] are claiming the application of an exemption to the general labeling requirements, and because they appear to be in the better position to come forward with evidence that the [device] works safely and effectively, we conclude that . . . claimants had the burden of proving that the perscription device exemption applied . . . .

Toftness, 731 F.2d at 1262.

the practical realities of veterinary medicine. To expect an individual veterinarian to subject himself to the many years and millions of dollars involved in the approval process is clearly unrealistic and unreasonable. The veterinarian prescribes and compounds drugs as the need arises in the animals under his care. Such individual use of various drugs does not warrant the filing for a new animal drug application. In fact, the director of the FDA's Center for Veterinary Medicine, Dr. Gerald Guest, testified at a deposition[8] that he was unaware of any veterinarian who has ever obtained a new animal drug approval for a drug to be used in his practice.

In *Ruley v. Nevada Bd. of Prison Comm'rs*, 628 F.Supp. 108 (D.Nev.1986), the Court correctly stated:

> An administrative agency that administers a statute does not have the power to make law; rather, its authority is to adopt regulations to carry into effect the will of the legislature as expressed by the statute. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213-14, 96 S.Ct. 1375, 1390-91, 47 L.Ed.2d 668 (1976). It follows that the agency may not make a rule or regulation that is out of harmony with or goes beyond the scope of its statutory grant of authority.

Ruley, 628 F.2d at 111; *see also United States v. Richards*, 583 F.2d 491, 495 (10th Cir. 1978) ("the validity of regulations promulgated under an authorizing statute will be sustained [only if] they are 'reasonably related to the purposes of the enabling legislation.'"); *Bates v. United States*, 581 F.2d 575, 580 (6th Cir.1978).

Clearly, for the reasons given above, the regulation at issue is "out of harmony" with the statutory authority and "goes beyond the scope" of it. Congress has, throughout the history of the Act, shown great deference to the autonomy of the healing arts and has left to the states any necessary regulation. The FDA attempts in this cause to establish for the first time that it is empowered to con-

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[8] This deposition was taken in a separate but similar lawsuit pending in the District Court of New Jersey. *United States v. Algon Chemical, Inc.*, No. 87- 1820 (D.N.J. filed May 12, 1987).

trol an integral part of veterinary practice.[9] This is an unacceptable reading of the Act. Veterinarians need the freedom to prescribe and compound drugs according to the needs of its clients and not within the constraints which would be posed by the FDA's reading of the Act. Congress has *never* attempted to handcuff veterinarians in such a way and neither will this Court.

[4] Having found that the agency has overstepped its regulatory authority, the Court must now fashion a remedy. We must read the regulation as consistent with the statute to the extent possible. *See Bencivenga v. Western Pennsylvania Teamsters*, 763 F.2d 574 (3d Cir.1985). The regulation is consistent with the statute to the point of exempting bulk drugs from the general labeling requirements. However, with respect to this claimant-a seller of the bulk drugs to veterinarians-the limitation of the exemption (*i.e.*, that "new drugs" are not exempt) is unreasonable and arbitrary and, therefore, a nullity.

Thus, the Court finds that the exemption, of 21 C.F.R. § 201.122, from the labeling requirements, of 21 U.S.C. § 352(f)(1), does apply to exempt the bulk drugs at issue from the labeling requirements.

B. Applicability of Section 321(w)(3) to the Five Lots

[5] Consistent with the previous finding, the Court holds that the new animal drug provisions of the Act, specifically here § 321(w)(3), are not applicable to the five lots of Defendant articles ampicillin trihydrate, amoxicillin trihydrate, tetracycline HCL, streptomycin sulfate, and penicillin V potassium. This is true be-

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[9] By affidavit, Dr. Robert M. Clack, D.V.M. stated: "If veterinarians were allowed to use only products that FDA approved and at the level that FDA approved them, it would be impossible for us to do our professional work. FDA's approved drugs and approved labeling are not flexible and do not work in the real world of animal disease." The claimant has submitted several other affidavits from veterinarians attesting similarly. While the Court must give deference to the opinion of the regulatory agency, it also gives much credence to the opinions of learned veterinarians who are physically engaged in the practice of veterinary medicine and who must cope with the day to day problems in the field, as opposed to FDA officials who are not currently engaged in such day to day, hands on activity.

cause these are not finished dosage forms of the drugs. It is clear from the statutory scheme that Congress only intended the new drug provisons to apply to finished dosage forms.

In 21 U.S.C. § 321(w)(3), Congress defines the term new animal drug as "any drug *intended for use* in animals other than man, including any drug intended for use in animal feed but not including such animal feed . . . which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof. . . ." (emphasis added) Here, the drugs seized are not in finished dosage form and thus are not "intended for use" in animals in their present form. Thus, they are not "new animal drugs" as Congress used that term in the statute.[10] *Cf. United States v. Generix Drug Corp.*, 460 U.S. 453, 457, 103 S.Ct. 1298, 1300, 75 L.Ed.2d 198 (1983) (wherein the court held that an entire generic drug product was subject to new drug approval statute and not simply the active ingredient in the generic drug).

III. Conclusion

In summary, the Court finds (1) that the bulk drug exemption of 21 C.F.R. § 201.122 applies to bulk drugs supplied to veterinarians for use within the scope of the practice of their profession, and (2) the new animal drug definition of 21 U.S.C. § 321(w)(3) does not apply to such drugs.

Ergo, claimant's motion for summary judgment is ALLOWED. Conversely, Plaintiff's motion for summary judgment is DENIED. In accord with this ruling, the United States Marshal is hereby ordered to return the Defendant articles to the claimant.

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[10] It is interesting to note that review of the United States Code Annotated reveals that every lawsuit brought by the United States under § 321 involving new drugs or new animals drugs has involved a finished dosage drug. Clearly, the FDA is attempting to break into new areas of regulation with this as a test case.

JUDGMENT -- ORAL ARGUMENT

UNITED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604

July 27, 1988

Before

Hon. Frank H. Easterbrook, Circuit Judge
Hon. Daniel A. Manion, Circuit Judge
Hon. Jesse E. Eschbach, Senior Circuit Judge

UNITED STATES OF AMERICA,
Plaintiff-Appellant,

No. 88-1233

vs.

9/1 KG. CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, et al.,
Defendants-Appellees.

Appeal from the United States District Court for the Central District of Illinois, Springfield Division.
No. 86-C-3201
RICHARD MILLS, Judge

This cause was heard on the record from the United States District Court for the Central District of Illinois, Springfield Division, and was argued by counsel.

On consideration whereof, IT IS ORDERED AND ADJUDGED by this Court that the judgment of the said District Court in this cause appealed from be, and the same is hereby, REVERSED, with costs, in accordance with the opinion of this Court filed this date.

UNITED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604

September 6, 1988

Before

Hon. Frank H. Easterbrook, Circuit Judge
Hon. Daniel A. Manion, Circuit Judge
Hon. Jesse E. Eschbach, Senior Circuit Judge

UNITED STATES OF AMERICA,
Plaintiff-Appellant,

No. 88-1233

vs.

9/1 KG. CONTAINERS, MORE OF LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE,
Defendants-Appellees.

Appeal from the United States District Court for the Central District of Illinois, Springfield Division.
No. 86-3201
Richard Mills, Judge

ORDER

Defendants-Appellees filed a petition for rehearing and suggestion of rehearing en banc on August 10, 1988. No judge in regular active service has requested a vote on the suggestion of rehearing en banc, and all of the judges on the panel have voted to deny rehearing. The petition for rehearing is therefore DENIED.

§ 321. Definitions; generally

For the purposes of this chapter--

(w) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,--

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions; or

(3) which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug on the grounds that (A) the requirement of certification of batches of such drug, as provided for in section 360b(n) of this title, is not necessary to insure that the objectives specified in paragraph (3) thereof are achieved and (B) that neither subparagraph (1) nor (2) of this paragraph (w) applies to such drug.

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded--

Directions for use and warnings on label

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological con-

ditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device,is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

§ 360b. **New animal drugs--Unsafe new animal drugs and animal feed containing such drugs; conditions of safety; exemption of drugs for research**

(a)(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 351(a)(5) and section 342(a)(2)(D) of this title unless--

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug,

(B) such drug, its labeling, and such use conform to such approved application, and

(C) in the case of a new animal drug subject to subsection (n) of this section and not exempted therefrom by regulations it is from a batch with respect to which a certificate or release issued pursuant to subsection (n) is in effect with respect to such drug.

A new animal drug shall also be deemed unsafe for such purposes in the event of removal from the establishment of a manufacturer, packer, or distributor of such drug for use in the manufacture of animal feed in any State unless at the time of such removal such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee--

(i) is the holder of an approved application under subsection (m) of this section; or

(ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of an approved application under subsection (m) of this section.

(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed, be deemed unsafe for the purposes of section 351(a)(6) of this title unless--

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such drug, as used in such animal feed,

(B) there is in effect an approval of an application pursuant to subsection (m)(1) of this section with respect to such animal feed, and

(C) such animal feed, its labeling, and such use conform to the conditions and indications of use published pursuant to subsection (i) of this section and to the application with respect thereto approved under subsection (m) of this section.

(3) A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of section 351(a)(5) or (6) of this title if such article is for investigational use and conforms to the terms of an exemption in effect with respect thereto under subsection (j) of this section.

Filing application for uses of new animal drugs; contents

(b) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe and effective for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter)

of animals to which such drug (directly in or on animal feed) is intended to be administered, as the Secretary may require; (6) specimens of the labeling proposed to be used for such drug,or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant; (7) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and (8) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe.

§ 201.122 Drugs for processing, repacking, or manufacturing

A drug in a bulk package, except tablets, capsules,or other dosage unit forms, intended for processing, repacking, or use in the manufacture of another drug shall be exempt from section 502(f)(1) of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking"; and, if in substantially all dosage forms in which it may be dispensed it is subject to section 503(b)(1), the statement "Caution: Federal law prohibits dispensing without prescription". This exemption and the exemption under § 201.120 may be claimed for the same article. But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:

(a) An approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder by persons named in the application, and, for a new drug substance, the export of it by such persons under § 314.410 of this chapter; or

(b) If no application is approved with respect to such new drug or new animal drug, the label statement "Caution: For

manufacturing, processing, or repacking" is immediately supplemented by the words "in the preparation of a new drug or new animal drug limited by Federal law to investigational use," and the delivery is made for use only in the manufacture of such new drug or new animal drug limited to investigational use as provided in § 312.1 or § 511.1 of this chapter; or

(c) A new drug application or new animal drug application covering the use of the drug substance in the production and marketing of a finished drug product has been submitted but not yet approved or disapproved, the bulk drug is not exported, and the finished drug product is not further distributed after it is manufactured until after the new drug application or new animal drug application is approved.

UNITED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604

September 30, 1988

Before

Hon. Frank H. Easterbrook, Circuit Judge

UNITED STATES OF AMERICA,
Plaintiff-Appellant,

No. 88-1233

vs.

9/1 KG. CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, et al.,
Defendants-Appellees.

Appeal from the United States District Court for the Central District of Illinois, Springfield Division.
No. 86 C 3201
Judge Richard Mills

This matter comes before the court for its consideration of the following documents:

1. "APPELLEES' MOTION TO STAY THE MANDATE" filed herein on September 13, 1988, by counsel for the appellees.
2. "GOVERNMENT'S MEMORANDUM IN OPPOSITION TO APPELLEES' MOTION TO STAY THE MANDATE" filed herein on September 23, 1988, by counsel for the appellant.

On consideration thereof,

IT IS ORDERED that the mandate in this appeal shall be STAYED to and including October 12, 1988. If during the period of the stay, the clerk of the Supreme Court of the United States notifies the clerk of this court that the defendants have filed a petition for a writ of certiorari, the stay shall continue until final disposition of the petition by the Supreme Court. No bond shall be required. Accordingly,

IT IS ORDERED that the APPELLEES' MOTION TO STAY THE MANDATE is GRANTED.

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,

Plaintiff,

Civil Action No. 87-1820

v.

ALGON CHEMICAL INC., a corporation;
and EDWARD LATINSKY, an individual,

Defendant.

APPEARANCES:

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BISSELL, *District Judge*

These cross-motions arise out of a Complaint filed on May 12, 1987 by the United States of America ("United States") against Algon Chemical, Inc. ("Algon") and Edward B. Latinsky, President of Algon. In this cause, the United States sought preliminary and permanent injunctive relief against the distribution in interstate commerce of 13 lots of bulk drugs[1] in contravention of § 331(a), (c)[2] of the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.*, and temporary, preliminary and permanent injunctive relief against the receipt and distribution of similar drugs in future contravention of the Act. The Court ordered the defendants to show cause as to why an order should not be entered issuing a preliminary and permanent injunction restraining them from violation of the Act. After oral argument on May 28, 1987, the Court, finding no material issue of fact, dismissed plaintiff's application for preliminary injunction and *sua sponte* ordered the parties to file cross-motions for summary judgment.

Plaintiff's Complaint alleges that the drugs are not labeled with adequate directions for use and are, therefore, misbranded within the meaning of 21 U.S.C. § 352(f)(1). Additionally, plaintiff alleges that one of the lots of drugs, penicillin, is an unapproved new animal drug within the meaning of 21 U.S.C. § 321(w)(3),[3] and therefore is adulterated under 21 U.S.C. § 360 (a)(1)(A)[4] and

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[1] The drugs are bulk drugs intended for further processing for use on animals. They include five lots of dimetridazole; two lots each of levamisole and nitrofurazone; and one lot each of penicillin, sulfamethazazole, lincomycin and oxytetracycline.

[2] Title 21 U.S.C. § 331: The following acts and the causing thereof are hereby prohibited: (a) [t]he introduction or delivery for introduction into interstate commerce of any ... drug ... that is adulterated or misbranded. ... (c) [t]he receipt in interstate commerce of any ... drug ... that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

[3] Plaintiff's Complaint states "penicillin, is adulterated within the meaning of 21 U.S.C. § 351(a)(5) in that it is a new animal drug within the meaning of 21 U.S.C. § 321(w)(1)." The correct section, 21 U.S.C. § 321(w)(3), is cited in Plaintiff's Brief at p. 10.

§ 351(a)(5).[5] The United States brings this proceeding under 21 U.S.C. § 332(a) which vests the United States District Courts with jurisdiction to enjoin and restrain violations of the Act.

The defendant, Algon, argues that the 13 lots of drugs are exempt from the labeling requirements of § 352(f)(1) of the Act by virtue of an exempting regulation, 21 C.F.R. § 201.122. Additionally, defendant argues that the same exempting regulation serves to make § 321(w)(3) inapplicable to the seized penicillin.

Presently before the Court are cross-motions for summary judgment pursuant to Fed. R. Civ. P. 56. On a motion for summary judgment, "[t]he judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The parties, in moving for summary judgment, have agreed that there exist no genuine issues of material fact.[6] The Court will proceed therefore, upon consideration of the pleadings and affidavits submitted, to determine which party is entitled to judgment as a matter of law.

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[4] "A new animal drug shall, with respect to any particular use or intended use ... be deemed unsafe for the purposes of [351(a)(5)] ... unless -- (A) there is in effect an approval of an application filed ... with respect to such use or intended use of such drug." 21 U.S.C. § 360(b)(1)(A).

[5] "A drug ... shall be deemed to be adulterated -- if it is a new animal drug which is unsafe within the meaning of section [360(b)]." 21 U.S.C. § 351(a)(5).

[6] Each party has submitted conflicting statements from practicing veterinarians attesting to (1) the necessity of having access to bulk drugs for successful practice, and (2) the public health risk posed by the use of these drugs. However, these statements do not raise material issues in that they do not address the questions of whether there have been violations of the Food, Drug and Cosmetic Act or whether any alleged violation would continue absent an injunction. *See United States v. Sumitomo Shoji, New York, Inc.*, 534 F.2d 320, 324 (C.C.P.A. 1976) (where an issue of fact is not relevant to the controlling legal question, it is not material so as to preclude summary judgment.)

THE FACTS

Algon has been engaged in receiving and selling in interstate commerce bulk pharmaceutical and chemical supplies for approximately eight years. Drugs that are in bulk form require further processing before actual use. The 13 lots of bulk drugs in question were purchased by Algon after importation into the United States by ICC Industries, and were stored by the NBC Warehouse and Storage Co. in Garfield, New Jersey. These bulk drugs were intended solely for the use of veterinarians in the practice of veterinary medicine. To prevent Algon from shipping the drugs, the Food and Drug Administration ("FDA") requested that the State of New Jersey embargo the drugs under state law until the FDA could obtain relief in federal court.[7] The drugs were placed under embargo beginning September 3, 1986.

Prior to imposition of the embargo, Algon shipped portions of the 13 lots to, among others, Schuyler Laboratories, Rushville, Illinois and Brinton Veterinary Clinic, Willmar, Minnesota. [8] Schuyler, Algon's principal customer, resells the drugs to veterinarians.[9] None of the parties involved -- Algon, Schuyler, Borge and their veterinarian consignees -- hold FDA approvals for use of the drugs.

Two of the embargoed articles were in containers bearing cautionary labels stating "[t]o be used only for manufacturing, processing or repacking." The remaining articles bore labeling indicating only the name of the drug and its origin. None of these drug items were accompanied by labeling that indicated directions for use.

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[7] The FDA sought state embargo because the Act does not provide for administrative detention. Plaintiff's Brief, p. 5 n. 3. Approximately $300,000 worth of bulk chemicals have been embargoed by the State of New Jersey.

[8] Before the embargo Algon also sold a lot of dimetridazole to Borge Laboratories which in turn sold portions of the lot to two veterinary clinics.

[9] The government seized several lots of drugs owned by Schuyler under 21 U.S.C. § 334. The case was litigated in favor of Schuyler. *See United States v. 9/1 KG Containers . . . an Article of Drug for Veterinary Use*, 674 F. Supp. 1344 (C.D. Ill. 1987).

THE LAW

A. Labeling Under § 352(f)(1).

In its Complaint, plaintiff alleges that defendant introduced or delivered for introduction into interstate commerce drugs which were misbranded within the meaning of 21 U.S.C. § 352(f)(1). Section 352 provides that:

> [a] drug ... shall be deemed to be misbranded ...
>
> (f) [u]nless its labeling bears (1) adequate directions for use; ... *Provided*, that where any requirement of clause (1) of this paragraph, as applied to any drug ... is not necessary for the protection of the public health, the Secretary *shall* promulgate regulations exempting such drug ... from such requirement.

(Emphasis supplied). The Secretary promulgated an exemption for bulk drugs in response to the mandatory proviso of § 352(f)(1):

> A drug in a bulk package, except tablets, capsules, or other dosage unit forms, intended for processing, repacking,or use in the manufacture of another drug shall be exempt from section 502 (f)(1) [21 U.S.C. § 352(f)(1)] of the act if its label bears the statement"Caution: For manufacturing, processing, or repacking"; ... But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:
>
> (a) [a]n approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder ...

21 C.F.R. § 201.122.

The limitation in 21 C.F.R. § 201.122 indicates that labeling requirements of 21 U. S. C. § 352(f)(1) are not suspended if a bulk drug is to be used in a finished article that is a new (animal) drug unless an approved new animal drug application covers the production and delivery of the drug substance to the application holder.

Defendant contends that its bulk drug materials,when shipped, are labeled "for manufacturing, processing or repacking" in conformity with the language prescribed in 21 C.F.R. § 201.122 and are therefore exempt from the labeling requirements because they are used by veterinarians to compound finished articles which are unapproved new animal drugs. The issue to be decided, therefore,is whether the exception to the exemption in 21 C.F.R. § 201.122 applies to the defendant in this case.

1. The Burden of Proof.

Plaintiff contends that defendant has the burden of proving that its bulk drugs are exempt from the labeling requirements of 21 U.S.C. § 352(f)(1) and that defendant cannot meet this burden. In *United States v. An Article of Device ... Toftness Radiation Detector*, 731 F.2d 1253(7th Cir. 1984), the court dealt with a similar situation in which defendant was relying on exemptions found in a series of regulations to remove it from the labeling requirements of 21 U.S.C. § 352(f)(1). After examining the language of the statute and appropriate regulations, the court concluded that the "party claiming entitlement to a statutory exemption bears the burden of proving the entitlement * * *unless placing the burden of proof [on the defendant] would be contrary to the [letter and intent] of the Act." *Id.* at 1260, 1261. The precise question for this Court is whether the exception to the exemption in 21 C.F.R. § 201.122 is consistent with the letter and intent of the Act under which it was enacted, thus requiring the defendant to prove that its bulk drugs are entitled to be exempt from the labeling requirements of § 352(f)(1).

2. The Legislative Scheme

The Food, Drug and Cosmetic Act was enacted in 1938, after years of deliberation. The legislative history of the Act demonstrates that Congress had no intention through passage of this Act to interfere with the practice of the healing arts[10] and that

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[10] S. Rep. No. 361, 74th Cong., 1st Sess., 3 (1935). *See Chaney v. Heckler*, 718 F.2d 1174, 1179 n. 13 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985).

all the healing arts "licensed by law in the various states"should be accorded this independence.[11] The Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat 781 (1962), expanded the FDA's authority in carrying out the intent of the Act, however, certain notable exclusions from this expanded authority indicated Congress' intent that the FDA should not exercise the same type of control over the healing arts. Title 21 U.S.C. §374(a)(1)(B) empowers the FDA to"inspect ... such factory, warehouse, establishment, or vehicle ... in which prescription drugs ... are manufactured ... (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs ... are adulterated or misbranded within the meaning of this Act." Title 21 U.S.C. § 374(a)(2) states, however, that "[t]he provisions ... of this subsection shall not apply to -- ... (B) practitioners licensed by law to prescribe or administer drugs ... and who manufacture, prepare, propagate, compound, or process drugs ... solely for use in the course of their professional practice." Similarly, 21 U.S.C. § 360(b) requires that "every person ... engaged in the manufacture, preparation, propagation, compounding or processing of a drug or drugs ... register with the Secretary his name, [and] places of business." Once again, "practitioners licensed by law to prescribe or administer drugs ... and who manufacture, prepare, propagate, compound, or process drugs ... solely for use in the course of their professional practice" are exempt from the registration requirement. 21 U.S.C. § 360(g)(2). These exclusions apply to veterinarians as well as other practitioners of the healing arts.

In 1968 Congress amended the Food, Drug and Cosmetic Act with Animal Drug Amendments, Pub. L. No. 90-399, 82 Stat. 343 (Codified as 21 U.S.C. § 360b (1982)), intended to "merely consolidate provisions under existing law."[12] The amendments did not add much "new" law, but simply drew together in § 360b the requirements for drugs and certifiable antibiotics which had previously been scattered throughout the existing Act. The only new

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[11] S. Rep. No. 361, 74th Cong., 1st Sess., 5 (1935).

[12] S. Rep. No. 1308, 90th Cong., 2d Sess. 1, *reprinted in* 1968 U.S. Code Cong.& Admin. News 2608.

section was that dealing with drugs in feed, or the medicated feed section. Congress had the opportunity to alter substantially the provision of the Act pertaining to the regulation of animal drugs; however, it chose merely to consolidate the existing provisions into a more efficient format. There is nothing in the legislative history of the Animal Drug Amendments of 1968 indicating that they were intended to have any impact upon the practice of veterinary medicine.

In the instant case, the regulation in question exempts bulk drugs from the labeling requirements of 21 U.S.C. § 352(f)(1) unless the bulk drug will be used to produce a finished article which is a new drug. The "new drug" limitation can be avoided only if a new animal drug application covers the production and delivery of the drug to "the application holder." Since these bulk drugs are being produced for and delivered to veterinarians, the regulation, in effect, requires that veterinarians must be holders of new animal drug approvals. In order to apply for and become holders of new animal drug approvals, veterinarians would have to comply with registration and inspection provisions of the Act from which they have been expressly exempted. This is an unreasonable expectation given Congress' consistent approach of staying out of the regulation of the healing arts.

"The validity of regulations promulgated under an authorizing statute will be sustained so long as they are 'reasonably related to the purposes of the enabling legislation'." *United States v. Richards*, 583 F.2d 491, 495 (10th Cir. 1978) (quoting *Thorpe v. Housing Authority of the City of Durham*, 393 U.S. 268, 280-81 (1969)).

United States v. 911 KG Containers ... Article of Drug for Veterinary Use, 674 F. Supp. 1344 (C.D. Ill. 1987),[13] presenting a fact pattern very similar to the case at bar, deals directly with the validity of 21 C.F.R. § 201.122. The court stated that it "makes no sense for Congress to grant [an exemption from registration for

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[13] An opinion was rendered in favor of defendant on December 8, 1987. The court subsequently granted the government's motion for a stay of judgment pending appeal to the United States Court of Appeals for the Seventh Circuit.

those who prescribe or administer drugs and who compound, or process drugs solely for use in the course of their professional practice] if it then takes away the very drugs that would be compounded." *Id.* at 1349. The court found the regulation to be clearly "inconsistent and out of harmony with the statute's intent as manifested by Congress." *Id.* at 1349. Furthermore, the Court found that requiring the defendant to carry the burden of showing a regulatory exemption applies to its situation was unreasonable. In order to benefit from the labeling exemption defendant would have to demonstrate that "(1) the finished product in which the bulk drug is used is not a new drug; or (2) that if it is a new drug, a new animal drug application has been secured." *Id.* at 1349. First, the court noted that neither the plaintiff nor the defendant would be able to show that the finished product was not a new drug because, up until the time of compounding by the individual veterinarian, there was no finished product. Second, defendant could not possibly apply for a new drug approval because he has no idea what drug will be produced when veterinarians compound a finished product from bulk drugs. Finally, to require veterinarians to apply for new drug approvals is simply unrealistic and inconsistent with Congress' intent to stay out of the regulation of veterinary medicine. After noting that a regulation must be read as consistent with the statute,[14] the court concluded that the "regulation [was] consistent with the statute to the point of exempting bulk drugs from the general labeling requirements. However, ... the limitation of the exemption (*i.e.*, that 'new drugs' are not exempt) [was] unreasonable and arbitrary and therefore, a nullity." *Id.* at 1350.[15]

The present case is nearly identical to *United States v. 9/1 KG Containers* in that the United States alleges that defendant's drugs are misbranded under the provisions of 21 U.S.C. § 352 (f)(1) and defendant relies on the exempting provisions of 21 C.F.R. § 201.122 to remove its bulk drugs from the labeling requirements

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[14] *See Bencivenga v. Western Pa. Teamsters*, 763 F.2d 574 (3d Cir. 1985).

[15] *See Fowler v. Gage*, 301 F.2d 775, 778-79 (10th Cir. 1962). A portion of a regulation may be severed so long as the remainder of the regulation is valid.

of § 352(f)(1). Here, as in that case, to require defendant to show that the finished product in which its bulk drugs are to be used is *not* a new drug; or to show that if the finished product is a new drug, a new animal drug application has been secured by the veterinarian receiving the bulk drug, is unreasonable. The Court finds that 21 C.F.R. § 201.122 places upon the defendant the impossible burden of demonstrating that the exemption applies to its bulk drugs. The Court also finds that the exceptions to the basic exemption are not consistent with the statute under which this regulation was promulgated. Therefore, in order to give a reasonable meaning to the exempting regulation, consistent with the Act, the Court finds that only that portion which exempts bulk drugs from the labeling requirements of 21 U.S.C. § 352(f)(1) applies to bulk drugs supplied for use in the practice of veterinary medicine.

B. Applicability of § 321(w)(3) to the Bulk Drug Penicillin.

Plaintiff alleges that one of the drug lots, penicillin, is an unapproved new animal drug within the meaning of 21 U.S.C. § 321(w)(3), and therefore is adulterated under 21 U.S.C. § 360(a)(1) and § 351(a)(5). Defendant contends that all § 321(w)(3) does is to make penicillin subject to the new animal drug requirements when it is manufactured in a form suitable for commercial purposes. The issue to be decided then is whether *bulk* penicillin is in a form intended for use in animals so as to be an new animal drug subject to the provisions of § 360(a)(1) and § 351(a)(5).

Section 321(w)(3) provides that "[t]he term 'new animal drug' means any drug *intended for use for animals* other than man ... which drug is composed wholly or partly of any kind of penicillin." (Emphasis supplied). The language of the statute clearly indicates that the term "new animal drug" applies only to drugs which are manufactured in a finished dosage form and not to bulk ingredients used in compounding by veterinarians. Here, the drugs under embargo are not in finished dosage forms (*e.g.*, capsules, tablets) and are not "intended for use" in their present form. Instead, they are intended solely for the use of veterinarians who will

compound them into medicines to be used in their practices. "Thus they are not 'new animal drugs' as Congress used that term in the statute."[16] For this reason, the Court finds that the new animal drug provisions of § 321(w)(3) are not applicable to the embargoed lot of penicillin; therefore, it is not adulterated within the meaning of 21 U.S.C. § 360(a)(1)(A) and § 351(a)(5).

Although plaintiff's Complaint specifically cites only penicillin as being adulterated under the provisions of 21 U.S.C. § 321(w)(3), the Court finds that none of these bulk drugs are "intended for use" in animals because they are not in final dosage forms, and are therefore not "adulterated."

CONCLUSION

The Court finds that the bulk drug exemption to 21 U.S.C. § 352(f)(1)provided in 21 C.F.R. § 201.122 applies to the bulk drugs which are the subject of the present action and are supplied to veterinarians solely for compounding into medicines used in their practices, and that the "new animal drug" provision of 21 U.S.C. § 321(w)(3) does not apply to the embargoed lot of penicillin. Accordingly, the Court grants defendant's motion for summary judgment.

/s/ John W. Bissell
John W. Bissell
United States District Judge

DATED: April 12, 1988

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[16] *United States v. 9/1 KG Containers ... Articles of Drug for Veterinary Use, supra*, held that it was clear from the "statutory scheme that Congress only intended the new drug provisions to apply to finished dosage forms." 674 F. Supp. at 1351.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,

Plaintiff,

Civil Action No. 87-1820

v.

ALGON CHEMICAL INC., a corporation; and EDWARD LATINSKY, an individual,

Defendants.

ORDER

For the reasons set forth in the Court's Opinion filed herewith,

It is on this 12th day of April, 1988,

ORDERED that defendants' motion for summary judgment be and it hereby is granted, and this action be and it hereby is dismissed, with prejudice and with costs.

/s/ John W. Bissell
John W. Bissell
United States District Judge